

COPY

-Application

Karing Harts

Cardiology

CN1311-046

November 15, 2013

Melanie M. Hill, Executive Director
Tennessee Health Services and Development Agency
Frost Building, Third Floor
161 Rosa Parks Boulevard
Nashville, Tennessee 37203

RE: CON Application for Cardiac PET Service, by Karing Hearts Cardiology
Johnson City, Washington County

Dear Mrs. Hill:

This letter transmits an original and two copies of the subject application. The affidavit and filing fee are enclosed.

This application intends to replace CN1304-014, which was approved by the HSDA Board in July. That CON was for the relocation of Molecular Imaging Alliance's existing Cardiac PET ODC from Gray to Johnson City, into a medical office building occupied by Karing Hearts Cardiology--the physician practice that has always been the largest referral source for this ODC.

The owner of the ODC, Mr. Robert Gregory, now wants to exit the business and turn it over to Karing Hearts Cardiology. Karing Hearts has decided to offer this service as a service of the practice, rather than to acquire ODC ownership. The purpose of this application is simply to authorize Cardiac PET as a service of the practice; and when that occurs, Mr. Gregory will turn in CN1304-014 to be voided.

Because this is no more than a change in applicant for a type of equipment and service approved in two prior reviews, the applicant requests Consent Calendar review.

I am the contact person for this project. Byron Trauger is legal counsel. Please advise me of any additional information you may need. We look forward to working with the Agency on this project.

Respectfully,



John Wellborn
Consultant

**KARING HEARTS
CARDIOLOGY, PLLC**

**CERTIFICATE OF NEED APPLICATION
TO ACQUIRE A CARDIAC PET SCANNER
FOR THE PRACTICE**

**Johnson City, Washington County
Filed April 2013**

PART A

1. Name of Facility, Agency, or Institution

Karing Hearts Cardiology Cardiac PET Service		
<i>Name</i>		
701 State of Franklin Road, Suite 2	Washington	
<i>Street or Route</i>	<i>County</i>	
Johnson City	TN	37604
<i>City</i>	<i>State</i>	<i>Zip Code</i>

2. Contact Person Available for Responses to Questions

John Wellborn		Consultant	
<i>Name</i>		<i>Title</i>	
Development Support Group		jwdsg@comcast.net	
<i>Company Name</i>		<i>E-Mail Address</i>	
4219 Hillsboro Road, Suite 210	Nashville	TN	37215
<i>Street or Route</i>	<i>City</i>	<i>State</i>	<i>Zip Code</i>
CON Consultant	615-665-2022	615-665-2042	
<i>Association With Owner</i>	<i>Phone Number</i>	<i>Fax Number</i>	

3. Owner of the Facility, Agency, or Institution

Karing Hearts Cardiology, PLLC		
<i>Name</i>		
701 State of Franklin Road, Suite 2	Washington	
<i>Street or Route</i>	<i>County</i>	
Johnson City	TN	37604
<i>City</i>	<i>State</i>	<i>Zip Code</i>

4. Type of Ownership or Control (Check One)

A. Sole Proprietorship		F. Government (State of TN or Political Subdivision)	
B. Partnership		G. Joint Venture	
C. Limited Partnership		H. Limited Liability Company	
D. Corporation (For-Profit)		I. Other (Specify): Professional	
E. Corporation (Not-for-Profit)		Limited Liability Company	x

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS

5. Name of Management/Operating Entity (If Applicable) **NA**

<i>Name</i>		
<i>Street or Route</i>	<i>County</i>	
<i>City</i>	<i>State</i>	<i>Zip Code</i>

6. Legal Interest in the Site of the Institution (Check One)

A. Ownership	<input type="checkbox"/>	D. Option to Lease	<input type="checkbox"/>
B. Option to Purchase	<input type="checkbox"/>	E. Other (Specify):	<input type="checkbox"/>
C. Lease of 5 Years	<input checked="" type="checkbox"/>		<input type="checkbox"/>

7. Type of Institution (Check as appropriate—more than one may apply)

A. Hospital (Specify): General	<input type="checkbox"/>	I. Nursing Home	<input type="checkbox"/>
B. Ambulatory Surgical Treatment Center (ASTC) Multi-Specialty	<input type="checkbox"/>	J. Outpatient Diagnostic Center	<input type="checkbox"/>
C. ASTC, Single Specialty	<input type="checkbox"/>	K. Recuperation Center	<input type="checkbox"/>
D. Home Health Agency	<input type="checkbox"/>	L. Rehabilitation Center	<input type="checkbox"/>
E. Hospice	<input type="checkbox"/>	M. Residential Hospice	<input type="checkbox"/>
F. Mental Health Hospital	<input type="checkbox"/>	N. Non-Residential Methadone	<input type="checkbox"/>
G. Mental Health Residential Facility	<input type="checkbox"/>	O. Birthing Center	<input type="checkbox"/>
H. Mental Retardation Institutional Habilitation Facility (ICF/MR)	<input type="checkbox"/>	P. Other Outpatient Facility (Specify):	<input type="checkbox"/>
	<input type="checkbox"/>	Q. Other (Specify): Private Practice	<input checked="" type="checkbox"/>

8. Purpose of Review (Check as appropriate—more than one may apply)

A. New Institution	<input type="checkbox"/>	G. Change in Bed Complement Please underline the type of Change: Increase, Decrease, Designation, Distribution, Conversion, Relocation	<input type="checkbox"/>
B. Replacement/Existing Facility	<input type="checkbox"/>	H. Change of Location	<input type="checkbox"/>
C. Modification/Existing Facility	<input type="checkbox"/>	I. Other (Specify):	<input type="checkbox"/>
D. Initiation of Health Care Service as defined in TCA Sec 68-11-1607(4) (Specify) Cardiac PET	<input checked="" type="checkbox"/>		<input type="checkbox"/>
E. Discontinuance of OB Service	<input type="checkbox"/>		<input type="checkbox"/>
F. Acquisition of Equipment	<input checked="" type="checkbox"/>		<input type="checkbox"/>

9. Bed Complement Data**NA*****(Please indicate current and proposed distribution and certification of facility beds.)***

	Current Licensed Beds	CON approved beds (not in service)	Staffed Beds	Beds Proposed (Change)	TOTAL Beds at Completion
A. Medical					
B. Surgical					
C. Long Term Care Hosp.					
D. Obsetrical					
E. ICU/CCU					
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric					
J. Child/Adolesc. Psych.					
K. Rehabilitation					
L. Nursing Facility (non-Medicaid certified)					
M. Nursing Facility Lev. 1 (Medicaid only)					
N. Nursing Facility Lev. 2 (Medicare only)					
O Nursing Facility Lev. 2 (dually certified for Medicare & Medicaid)					
P. ICF/MR					
Q. Adult Chemical Dependency					
R. Child/Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL					

10. Medicare Provider Number:	103G706288
Certification Type:	group medical practice
11. Medicaid Provider Number:	1523022
Certification Type:	group medical practice

12. & 13. See page 4

A.12. IF THIS IS A NEW FACILITY, WILL CERTIFICATION BE SOUGHT FOR MEDICARE AND/OR MEDICAID?

This is an existing physician practice that participates in both Medicare and TennCare/Medicaid, including Medicaid in adjoining Virginia.

A.13. IDENTIFY ALL TENNCARE MANAGED CARE ORGANIZATIONS / BEHAVIORAL HEALTH ORGANIZATIONS (MCO'S/BHO'S) OPERATING IN THE PROPOSED SERVICE AREA. WILL THIS PROJECT INVOLVE THE TREATMENT OF TENNCARE PARTICIPANTS? Yes IF THE RESPONSE TO THIS ITEM IS YES, PLEASE IDENTIFY ALL MCO'S WITH WHICH THE APPLICANT HAS CONTRACTED OR PLANS TO CONTRACT.

DISCUSS ANY OUT-OF-NETWORK RELATIONSHIPS IN PLACE WITH MCO'S/BHO'S IN THE AREA.

Table One: Contractual Relationships with Service Area MCO's	
Available TennCare MCO's / Medicaid	Applicant's Relationship
BlueCare	contracted
United Community Healthcare Plan (formerly AmeriChoice)	contracted
TennCare Select	contracted
Virginia Medicaid	contracted

SECTION B: PROJECT DESCRIPTION

B.I. PROVIDE A BRIEF EXECUTIVE SUMMARY OF THE PROJECT NOT TO EXCEED TWO PAGES. TOPICS TO BE INCLUDED IN THE EXECUTIVE SUMMARY ARE A BRIEF DESCRIPTION OF PROPOSED SERVICES AND EQUIPMENT, OWNERSHIP STRUCTURE, SERVICE AREA, NEED, EXISTING RESOURCES, PROJECT COST, FUNDING, FINANCIAL FEASIBILITY AND STAFFING.

Proposed Services and Equipment

- LifeScan Tennessee, LLC, dba Molecular Imaging Alliance, owns and operates a licensed Outpatient Diagnostic Center (“ODC”) in Gray, Tennessee, in northwest Washington County. It provides cardiac PET services. It is the only cardiac PET facility in Upper East Tennessee. In July 2013, it was unanimously granted CN1304-014 to relocate with one leased Cardiac PET unit to a smaller office space 10 miles east, at 701 North State of Franklin Road, Johnson City, TN. This location adjoins the physician practice of Karing Hearts Cardiology, which has always been the largest referral source for this Cardiac PET ODC. Implementation of that relocation is suspended, pending HSDA decision on this application.
- The ODC’s owner, Mr. Robert Gregory, is seeking to exit the ODC business and to terminate its lease of the PET unit it now operates, without implementing the ODC at the new location in Johnson City. The physicians of Karing Hearts Cardiology seek to lease that same PET unit to offer it as a service of their practice, so that the approved relocation of the service from Gray to Johnson City may be implemented. They do not want to acquire and operate the ODC that holds the CON (which could be done without further CON approval). If Karing Hearts Cardiology is approved to offer this service and implements that approval, then Molecular Imaging Alliance will turn in CN1304-014 to be voided.
- The project will serve counties already approved for this type of service. It will not change the scope of services, or the costs already approved for this service. This will be the third CON review for the Cardiac PET service, so consent calendar review is respectfully requested.
- The cardiac PET service will be housed in medical practice space, and will utilize practice staff consisting of a nuclear medicine tech, an RN (half time) and a receptionist (half time).

Ownership Structure

- The CON applicant is Karing Hearts Cardiology, PLLC, a Johnson City cardiology practice owned by Dr. Jeffrey Schoondyke, M.D. A second cardiologist, Dr. Melanie Davidson, joined the practice in late 2013. She is also an established cardiologist in the service area.

Service Area

- The Cardiac PET ODC was granted CON approval in CY2007, to provide cardiac PET services to all of Upper East Tennessee. It has been doing that for more than five years.

This project under physician ownership will not serve counties that were not included in prior reviews of this project. Its Tennessee primary service area (85.3% of referrals) will be Washington, Carter, and Unicoi Counties, with additional patients coming from Sullivan, Greene, and Johnson Counties, and from other nearby counties and States.

Need & Existing Resources

- This new application is required to convert the approved cardiac PET service from an ODC-based service to a physician practice-based service, at the same site the HSDA approved in July. The need for cardiac PET services in this area was reviewed and established at the time of the ODC's original approval in 2007 (CN0701-010). The need to relocate the service from Gray to Johnson City, with one cardiac PET unit, was established by unanimous approval of CN1304-014 in July 2013.
- The need for filing another application arises from the CON holder's recent decision to exit the Outpatient Diagnostic Center business without implementing CN1304-014, and the need of physicians and patients in the service area for continuing access to cardiac PET scanning, at the location approved four months ago. Karing Hearts is willing to lease the cardiac PET equipment directly, and to offer the service at the previously approved location, but as part of its practice rather than as a separate licensed facility.
- Since 2007, the ODC in Gray has been the Upper East Tennessee region's only source of cardiac-specific PET units. It has operated two cardiac PET units. In July 2013, Wellmont Cardiology Services was granted CON approval to acquire one of the two units and move it to Kingsport; and that is being implemented. At the same meeting, LifeScan was approved to move its Molecular Imaging Associates ODC with the remaining PET unit to Johnson City. This new application is to convert the ODC-based PET to a physician-based PET. It will still be one of only two cardiac PET units available in Upper East Tennessee.

Project Cost, Funding, Financial Feasibility, and Staffing

- The estimated project cost for CON purposes, which includes an estimation of the value of leased space, and equipment (not capital cost items), is \$391,585. The actual capital cost for moving the PET system and renovating the proposed site will be only \$138,550. It will be funded by a loan from a local bank.
- Even at a future rate of growth much less than its 17% annual average growth since 2009, this service will operate with a positive margin from the time it opens as a physician office-based service. It is an established service in the region. The applicant cardiology group in the past has referred the great majority of its utilization, so its core of demand will not be diminished by this change of organization and ownership. It will be within an established cardiology practice that serves Medicare, TennCare, Medicaid, and uninsured patients.
- Under this medical practice's ownership, the cardiac PET service will have exactly the same staff that it has today, and was approved to have in CN1304-014. It will have the same Medical Director, Dr. Jeffrey Schoondyke. Its cardiac studies will be performed with the assistance of a nuclear medicine tech, and an RN and receptionist shared with the medical practice.

B.II. PROVIDE A DETAILED NARRATIVE OF THE PROJECT BY ADDRESSING THE FOLLOWING ITEMS AS THEY RELATE TO THE PROPOSAL.

B.II.A. DESCRIBE THE CONSTRUCTION, MODIFICATION AND/OR RENOVATION OF THE FACILITY (EXCLUSIVE OF MAJOR MEDICAL EQUIPMENT COVERED BY T.C.A. 68-11-1601 *et seq.*) INCLUDING SQUARE FOOTAGE, MAJOR OPERATIONAL AREAS, ROOM CONFIGURATION, ETC.

Ownership and Scope of the Project

The CON applicant is Karing Hearts Cardiology, PLLC, a cardiology practice established in Johnson City by Dr. Jeffrey Schoondyke, M.D., who is its sole member. A second cardiologist, Dr. Melanie Davidson, has recently joined the practice. She is also an established cardiologist in the service area.

The applicant proposes to lease from LifeScan Leasing, LLC (an equipment vendor) the GE Advance Nxi Cardiac PET system that the ODC in Gray currently leases, and to install it in the same part of the applicant's practice space that received approval as Cardiac PET ODC space under CN1304-014, just four months ago.

The proposed new location is very close to Johnson City Medical Center. There, it will be more convenient to patients referred from the Johnson City medical community, and it will be under the supervision of Karing Hearts Cardiology physicians.

Karing Hearts Cardiology will utilize the service for its patients. A lesser number of additional procedures will be performed for patients referred from other practices, unless Tennessee Department of Health licensure rules preclude such referrals to a PET service that is not licensed as an ODC.

The Project Site (Same As In Approved CN1304-014)

The project's address will be Karing Hearts Cardiology, 701 State of Franklin Road, Suite 2, Johnson City, Tennessee 37604. The building is owned by Dr. Jeffrey Schoondyke and his wife. The owners lease one end of the building to Karing Hearts Cardiology, PLLC, the medical practice of Dr. Schoondyke and Dr. Melanie Davidson.

Their medical practice occupies Suites One Two, and Three of the building, using Suite Two as its main entrance and address. Other non-related entities occupy other suites in the building.

Design of the Project

The practice itself will be providing the service, in space it already leases from the building owner. The “701” building has approximately 23,000 SF of space. Karing Hearts Cardiology currently leases 8,083 SF of the building. The proposed service will use a small amount of “dedicated” space and will share several support spaces with other services of the practice. Table Two-A below indicates the applicant’s space allocation for PET services. The PET and its control room are exclusively for use by PET patients; the other spaces are shared with other patients so they were allocated to this project at 50% of their floor space. The total space allocation for the project is 905 SF. (This was used to prorate the practice’s expenses for this project, in the Projected Data Chart .)

Table Two-A: Medical Practice Space Allocated to Cardiac PET Services			
Space	Square Footage	Percent Allocated	SF Allocation
Cardiac PET Room	328 SF	100%	328 SF
PET Control Room	147.25 SF	100%	147.25 SF
Patient Prep Room	165 SF	50%	82.5 SF
Hot Lab (Nuclear Med.)	56.25	50%	28.125 SF
Entry	215.25 SF	50%	107.625 SF
Reception	90.25 SF	50%	45.125 SF
Sub waiting	192 SF	50%	96 SF
Hallways / Circulation	141 SF	50%	70.5 SF
Total			905.125 SF

Source: Medical practice Management

The Cardiac PET service will utilize a cardiac PET camera room with an adjoining control room, and will share use of the practice’s nuclear medicine “hot lab”, a patient prep/uptake room, an entry, a reception/checkout desk, a sub-waiting area, and circulation space within the practice. The cardiac PET camera room, nuclear medicine room, and patient prep/uptake room are expensive to renovate, due to the need for radiation shielding in their walls, and strengthened floor footings in the camera room. A floor plan for the office’s PET services area and adjoining medical spaces is provided in Attachment B.IV in this application.

At Gray, the ODC that offers this service is accredited for Nuclear Medicine/Positive Emission Tomography (PET) services by the Intersocietal Accreditation Commission (IAC). The applicant medical practice will seek to maintain that accreditation at its Johnson City site when it takes over the service from the ODC.

Construction Cost

No new construction is required. An estimated 556 SF of the allocated area of 905 SF will require heavy renovation (shielding and some reinforced floor footings); the other 349 SF will be finished as medical office space, requiring only minor renovation. The overall renovation cost will be only \$110.50 PSF.

Table Two-B: Construction Costs of This Project		
	SF of Renovation	SF of New Construction
Square Feet Allocated	905 SF	0
Construction Cost	\$100,000	0
Constr. Cost PSF Allocated	\$110.50	0

Implementation Schedule and Hours of Operation

If granted CON approval before the end of February 2014, this relocation project can be open for patient service prior to December 31, 2014. Its first full calendar year will be CY2015. The current hours of operation (scheduled service) for the ODC in Gray are from 7 AM to 5 PM, on weekdays. This schedule will continue at the Karing Hearts Cardiology location.

Project Cost and Financing

The project's cost for CON review purposes--which includes the value of leased space and leased equipment--is estimated at \$391,585. The applicant's actual capital cost (for project design, construction, equipment, and the CON process) will be only \$138,550. This amount is available from a local bank (please see the bank's confirmation letter in the Attachments).

APPLICANTS WITH HOSPITAL PROJECTS (CONSTRUCTION COST IN EXCESS OF \$5 MILLION) AND OTHER FACILITY PROJECTS (CONSTRUCTION COST IN EXCESS OF \$2 MILLION) SHOULD COMPLETE THE SQUARE FOOTAGE AND COSTS PER SQUARE FOOTAGE CHART....

Not applicable.

PLEASE ALSO DISCUSS AND JUSTIFY THE COST PER SQUARE FOOT FOR THIS PROJECT.

This project requires only renovation of existing space, at an overall average cost of only \$110.50 PSF. The tables below compare that to renovation costs for the other two approved cardiac PET CON's in this region, and for several approved ODC's.

ODC renovation projects completed in 2008-2012 ranged from \$52-\$196 PSF construction cost, according to data from the HSDA Registry. Although the HSDA Registry did not compile a similar table for 2010-2012 due to the small number of ODC projects (5) completed in 2012, the Registry has supplied construction cost data for several of those projects; see Table Three-B below. Karing Hearts Cardiology's projected renovation cost of \$110.50 PSF compares well to these projects' costs.

Table Three-A: Outpatient Diagnostic Center Construction Cost PSF Years: 2008-2010			
	Renovated Construction	New Construction	Total Construction
1 st Quartile	\$51.55/sq ft	none	\$51.55/sq ft
Median	\$122.15/sq ft	none	\$122.15/sq ft
3 rd Quartile	\$196.46/sq ft	none	\$196.46/sq ft

Source: HSDA Registry. CON approved applications for years 2008 through 2010

Table Three-B: Outpatient Diagnostic Center Construction Cost PSF Years: 2012			
CON	ODC / Provider	Renovation Area	Construction Cost / sq ft
CN1010-046	Murfreesboro Diagnostic Imaging	9,587 SF	\$122.15/sq ft
CN1010-047	Cleveland Imaging	911 SF	\$269.91/sq ft
CN1103-008	E. TN Community Open MRI	795 SF	\$160.38/sq ft
CN1110-039	St. Thomas OP Imaging	7,737 SF	\$159.69/ sq ft
CN1110-039	Wellmont Cardiology Services Cardiac PET, Kingsport	2,080 SF	\$250 PSF
CN1304-014	Molecular Imaging ODC	847 SF	\$177 PSF
This Project	Karing Hearts Cardiology	905 SF	\$110.50 PSF

Source: HSDA Registry. CON approved ODC projects involving only renovation.

IF THE PROJECT INVOLVES NONE OF THE ABOVE, DESCRIBE THE DEVELOPMENT OF THE PROPOSAL.

Not applicable.

B.II.B. IDENTIFY THE NUMBER AND TYPE OF BEDS INCREASED, DECREASED, CONVERTED, RELOCATED, DESIGNATED, AND/OR REDISTRIBUTED BY THIS APPLICATION. DESCRIBE THE REASONS FOR CHANGE IN BED ALLOCATIONS AND DESCRIBE THE IMPACT THE BED CHANGE WILL HAVE ON EXISTING SERVICES.

Not applicable; no inpatient beds are affected by the project.

B.II.C. AS THE APPLICANT, DESCRIBE YOUR NEED TO PROVIDE THE FOLLOWING HEALTH CARE SERVICES (IF APPLICABLE TO THIS APPLICATION):

- 1. ADULT PSYCHIATRIC SERVICES**
- 2. ALCOHOL AND DRUG TREATMENT ADOLESCENTS >28 DAYS**
- 3. BIRTHING CENTER**
- 4. BURN UNITS**
- 5. CARDIAC CATHETERIZATION SERVICES**
- 6. CHILD AND ADOLESCENT PSYCHIATRIC SERVICES**
- 7. EXTRACORPOREAL LITHOTRIPSY**
- 8. HOME HEALTH SERVICES**
- 9. HOSPICE SERVICES**
- 10. RESIDENTIAL HOSPICE**
- 11. ICF/MR SERVICES**
- 12. LONG TERM CARE SERVICES**
- 13. MAGNETIC RESONANCE IMAGING (MRI)**
- 14. MENTAL HEALTH RESIDENTIAL TREATMENT**
- 15. NEONATAL INTENSIVE CARE UNIT**
- 16. NON-RESIDENTIAL METHADONE TREATMENT CENTERS**
- 17. OPEN HEART SURGERY**
- 18. POSITIVE EMISSION TOMOGRAPHY**
- 19. RADIATION THERAPY/LINEAR ACCELERATOR**
- 20. REHABILITATION SERVICES**
- 21. SWING BEDS**

A. Reason For Filing This Application

The project is for a Johnson City cardiology practice to acquire and operate a cardiac PET system for its patients, at the time the nearby ODC that currently provides that service ceases to operate.

There are several things that make this project unique with respect to “demonstrating need”. Briefly put, the need for the service, and its need to be at this same address in Johnson City, have been established by two prior CON reviews, the most recent of which was only four months ago, was unopposed, and received unanimous approval. This service is being reviewed again in a third application, only because the applicant physician group proposes to be the provider, replacing the ODC that was granted the two prior Certificates of Need. HSDA staff advises that this makes it a new project from a legal viewpoint. The ODC supports this application, because the ODC intends to close in the near future without implementing its CON to relocate to Johnson

City, and wants the service to continue to be available to area patients. So the following special facts should be considered:

(a) A cardiac PET service was approved by CN0701-010 as a needed service for multiple counties in the Upper East Tennessee region, including those proposed to be served in this application.

(b) This service has been operating five years in this area, serving hundreds of patients a year, most of whom were referred by the practice that is the applicant in this project.

(c) Cardiac PET continues to be a standard of diagnostic care for certain coronary conditions, with usage increasing steadily as it becomes physically more accessible than in the past.

(d) This service, now offered in nearby Gray, is already medically supervised by the cardiologist who is filing this application to move it to Johnson City.

(e) The service's relocation to Johnson City (as an ODC), to the same room and building in which this application proposes to offer the service, was approved unanimously by the HSDA only a few months ago (CN1304-014).

B. The Need for Cardiac PET Scanning and Its Difference from Conventional PET/CT

Cardiac PET studies and conventional PET/CT studies are both types of nuclear medicine tests, in which faintly radioactive substances with short half-lives are injected into the patient, revealing important diagnostic information as they move through the body and are tracked and measured on imaging equipment and computers. However, cardiac PET and conventional PET/CT studies differ significantly in several ways.

First, they differ in their scope of use. Conventional PET/CT units are almost entirely devoted to oncology and neurology studies (although they can be fitted with a software/hardware retrofit to do cardiac PET procedures). Cardiac PET systems are used for two purposes currently. One purpose is to identify blockages or circulation defects in heart arteries ("myocardial perfusion studies"). These studies provide such good diagnostic information that many patients can avoid having a subsequent diagnostic cardiac catheterization examination, which is an invasive surgical procedure that costs

more and imposes higher risks. The other purpose is to measure “myocardial viability” in patients with left ventricular dysfunction, to determine their candidacy for revascularization (arterial graft surgery). The cardiac PET test can show whether the heart tissue at the proposed site of surgery is too compromised to sustain and maintain an arterial graft. If it is, the patient can be spared an expensive, uncomfortable, and ultimately ineffective major surgery.

A second difference between conventional PET/CT and cardiac PET is their cost; a cardiac PET system is much less expensive. For example, in CY2012, HSDA Registry data shows that area PET units as a group billed an average gross charge of \$5,223 per PET scan. That year the ODC’s cardiac PET studies were billed at an average gross charge of only \$1,829--approximately one-third of the average of all PET units.

A third difference is that cardiac PET technology uses only two radiopharmaceuticals at the present time: either ammonia (N-13) or rubidium (R-82). The first has a half-life of only 10 minutes. The second has a half-life of only 75 seconds. This means that as a practical matter, the radiopharmaceutical supplier must be within a short drive of the cardiac PET unit, if not in the same building or room. The Gray ODC has been using N-13, supplied by a cyclotron in their building in Gray. The supplier can continue to provide N-13 to both scanners when they move to Karing Hearts in Johnson City, merely by manufacturing sufficient amounts of N-13 so that the required dosage is sufficient by the time it is administered. For example, if the delivery trip time plus administration of the pharmaceutical take 30 minutes, then an amount with the strength of eight doses of N-13 might be sent, so that after its radioactivity diminishes by 50% every 10 minutes, 1 full dose will remain available for injection. (“Dose” here is used in an illustrative sense; a patient may receive two doses as defined by nuclear medicine protocols.)

C. The Difference Between Cardiac PET and SPECT Nuclear Medicine Studies

For a large number of patients being diagnosed at a cardiology office, SPECT studies are scheduled to obtain diagnostic information similar to that provided by cardiac PET. However, it is increasingly accepted that cardiac PET yields superior diagnostic information.

The value of cardiac PET as a superior option to nuclear medicine SPECT studies (especially for patients of large body mass) has been consistently demonstrated by an array of clinical studies. Excerpts from several professional articles about its efficacy and cost savings are provided in the Attachments to this application--from the Journal of Nuclear Medicine, the Journal of American Cardiology, the Journal of Nuclear Cardiology, and Image (a professional magazine). As the case has built for this modality, more cardiology practices have begun to utilize it. The studies show that for patients considered likely to have coronary artery disease, myocardial perfusion PET is superior to SPECT in terms of image quality, interpretive certainty, and diagnostic accuracy. This is because cardiac PET has higher photon counts, improved spatial resolution, and attenuation correction in its images. With such improved information, the cardiologist can better evaluate the need (and probable efficacy) of additional "downstream" tests and interventions such as cardiac catheterizations and coronary artery bypass surgery.

D. The Need to Relocate The Service to Johnson City and to This Medical Practice

The applicant ODC is currently located in Gray, Tennessee, in the far western part of Washington County. The referring cardiologists who generate most of its utilization are based in Johnson City, in eastern Washington County.

There are three reasons for changing location of this service to Johnson City, and to Karing Hearts Cardiology's practice office.

First, the relocation will improve its physical accessibility to referring physicians, who must be onsite at the PET for medical supervision during their patients' cardiac PET scans. Being in Johnson City will shorten drive times for most of the ODC's patients and physicians. For example, the average drive time from Johnson City Medical Center to Gray is 12.3 miles (18 minutes), whereas the drive time from the Medical Center to the proposed site at 701 State of Franklin Road in Johnson City is only 0.8 miles (2 minutes). Round-trip savings for a physician coming from the Medical Center area will be approximately half an hour each time. For example, Dr. Jeffrey Schoondyke's practice is located in the 701 Building. With the service in his practice office, Dr. Schoondyke and his patients can eliminate drive time for the test. Even if no other physician ever refers to

the service, the time saved just for Dr. Schoondyke and Dr. Davidson and their hundreds of patients will be significant.

The second reason to relocate is to lower operating costs. The ODC that offers the service presently, and was planning to move it to Johnson City, has more space than it needs at Gray and was seeking to lower its lease costs with a relocation of only one PET system (its second PET system is being sold to another provider). If the service is transferred to Karing Hearts Cardiology as the provider, and placed in its practice office in space already under lease, the service will not have any rent payment, as the ODC would have. *(Note: rent is included as an expense on the Projected Data Chart in this application because the HSDA staff requires an allocation of existing rent to such a project, even though implementing the project will not increase existing rent.)*

The third and most compelling reason why this project is needed is that the ODC which is the Johnson City area's only source of cardiac PET services intends to go out of business, as soon as someone else can take over the equipment lease and provide the service. The logical successor to this ODC is the physician group that provides most of its referrals and provides its medical direction already, especially since their office was the place to which the ODC was approved to move in CN1304-014 last July. There is no health planning reason why this clinically significant service should be rendered unavailable to the eastern half of Upper East Tennessee, or should be kept in Gray; Karing Hearts Cardiology is prepared to ensure its continued availability for its patients, at a more convenient location.

E. Project Consistency With Health Planning Goals

The Guidelines for PET are addressed in a later section of this application. However, CON review involves many considerations other than the review criteria in the State Health Plan. This project, which allows Karing Hearts Cardiology to acquire and operate an existing cardiac PET service as a logical successor to its current operator, furthers several good planning objectives. Examples include the following.

1. Non-proliferation of services and major medical equipment: For reasons explained above, although a CON review is needed for a change in the legal provider

entity, in fact this cardiac PET system and service are not “new” in the sense of being additions of technology to the service area. They exist now; and they have been approved to move to the location that is proposed in Johnson City, albeit under other ownership. So this project cannot be said to duplicate existing services.

2. No change in service area: the equipment’s relocation will not cause it to serve any counties that are not already being served by the ODC in Gray.

3. Consistent with prior CON approvals: Existence of the service, and its relocation to this same address in Johnson City, have already been approved in two prior CON reviews.

4. Improves accessibility: Implementing a prior-approved relocation to Johnson City will increase the convenience of the service for both patients and physicians.

6. Improves efficiency: A cardiac PET test visit takes about an hour and 15 minutes, compared to three to six hours for a SPECT test visit. Switching to cardiac PET saves patients and their supervising physicians substantial time. The applicant believes that replacement of SPECT with cardiac PET will continue to increase if its location becomes more convenient for physicians and patients to use it, and as the service area population ages.

7. Cost savings: Studies are showing that cardiac PET rules out coronary artery bypass surgeries and cardiac catheterizations for many patients, and reduces the costs of care in such cases by as much as 30%. (See articles in the Attachments). So if the relocation from Gray to Johnson City boosts utilization of cardiac PET, the healthcare system will experience savings. In addition, the project cost for adding this to an existing physician office, without having to construct and license a separate Outpatient Diagnostic Center, or to pay lease expenses, offers a small cost advantage over the ODC relocation recently approved in CN1304-014.

B.II.D. DESCRIBE THE NEED TO CHANGE LOCATION OR REPLACE AN EXISTING FACILITY.

Not applicable.

B.II.E. DESCRIBE THE ACQUISITION OF ANY ITEM OF MAJOR MEDICAL EQUIPMENT (AS DEFINED BY THE AGENCY RULES AND THE STATUTE) WHICH EXCEEDS A COST OF \$1.5 MILLION; AND/OR IS A MAGNETIC RESONANCE IMAGING SCANNER (MRI), POSITRON EMISSION TOMOGRAPHY (PET) SCANNER, EXTRACORPOREAL LITHOTRIPTER AND/OR LINEAR ACCELERATOR BY RESPONDING TO THE FOLLOWING:

1. For fixed site major medical equipment (not replacing existing equipment):

a. Describe the new equipment, including:

- 1. Total Cost (As defined by Agency Rule);**
- 2. Expected Useful Life;**
- 3. List of clinical applications to be provided; and**
- 4. Documentation of FDA approval.**

b. Provide current and proposed schedule of operations.

2. For mobile major medical equipment:

- a. List all sites that will be served;**
- b. Provide current and/or proposed schedule of operations;**
- c. Provide the lease or contract cost;**
- d. Provide the fair market value of the equipment; and**
- e. List the owner for the equipment.**

3. Indicate applicant's legal interest in equipment (e.g., purchase, lease, etc.) In the case of equipment purchase, include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

- The PET scanner being relocated is a 2002 GE Advance Nxi PET scanner system including the camera, workstation, software, water chiller unit, lead door, in-lab furniture, and miscellaneous items in the lab and control room.
- The PET system was manufactured in 2002; its value is estimated at \$350,000.
- Its expected useful life is five years.
- It will perform cardiac PET examinations for both perfusion and blockage evaluations.
- Its current hours of operation in Gray are 7 am to 5 pm weekdays; this schedule will be maintained at its proposed new location in Johnson City.
- The applicant will lease the system. A draft of the lease applicable to this relocation is included in the Attachments.

B.III.A. ATTACH A COPY OF THE PLOT PLAN OF THE SITE ON AN 8-1/2" X 11" SHEET OF WHITE PAPER WHICH MUST INCLUDE:

- 1. SIZE OF SITE (IN ACRES);**
- 2. LOCATION OF STRUCTURE ON THE SITE;**
- 3. LOCATION OF THE PROPOSED CONSTRUCTION; AND**
- 4. NAMES OF STREETS, ROADS OR HIGHWAYS THAT CROSS OR BORDER THE SITE.**

PLEASE NOTE THAT THE DRAWINGS DO NOT NEED TO BE DRAWN TO SCALE. PLOT PLANS ARE REQUIRED FOR ALL PROJECTS.

See Attachment B.III.A.

B.III.B.1. DESCRIBE THE RELATIONSHIP OF THE SITE TO PUBLIC TRANSPORTATION ROUTES, IF ANY, AND TO ANY HIGHWAY OR MAJOR ROAD DEVELOPMENTS IN THE AREA. DESCRIBE THE ACCESSIBILITY OF THE PROPOSED SITE TO PATIENTS/CLIENTS.

The project site is very accessible to this practice's service area. Johnson City is the largest community in Washington County and is a tertiary healthcare referral destination, well known to patients living throughout the service area. The project site is reasonably accessible to all parts of upper East Tennessee by Federal and State highways. It is within minutes of I-26, which connects quickly to I-81, the major east-west highway in that region. US Highways 23 and 321, and Highways 67, 173, and 37 also provide access to other parts of the primary service area. Table Four below shows the average distances and drive times to principal cities in the project's primary and secondary service areas, and to the nearest alternative source of cardiac PET scans.

Table Four: Mileage and Drive Times Between Project and Major Communities in and Near the Primary Service Area			
From project at 701 N. State of Franklin Road, Johnson City, to:	County	Distance	Drive Time
<i>Primary Service Area</i>			
1. Elizabethton	Carter	12.8 mi.	23 min.
2. Erwin	Unicoi	18.2 mi	24 min.
3. Johnson City (the Medical Center)	Washington	0.8 mi.	2 min.
<i>Secondary Service Area</i>			
4. Greeneville	Greene	29.2 mi.	38 min.
5. Mountain City	Johnson	45.8 mi.	68 min.
5. City of Kingsport (center)	Sullivan	23.5 mi.	29 min.
6. Wellmont Cardiology Services Cardiac PET service, Kingsport	Sullivan	18.6 mi.	20 min.

Source: Google Maps, April and November 2013.

B.IV. ATTACH A FLOOR PLAN DRAWING FOR THE FACILITY WHICH INCLUDES PATIENT CARE ROOMS (NOTING PRIVATE OR SEMI-PRIVATE), ANCILLARY AREAS, EQUIPMENT AREAS, ETC.

See attachment B.IV.

IV. FOR A HOME CARE ORGANIZATION, IDENTIFY

- 1. EXISTING SERVICE AREA (BY COUNTY);**
- 2. PROPOSED SERVICE AREA (BY COUNTY);**
- 3. A PARENT OR PRIMARY SERVICE PROVIDER;**
- 4. EXISTING BRANCHES AND/OR SUB-UNITS; AND**
- 5. PROPOSED BRANCHES AND/OR SUBUNITS.**

Not applicable. The application is not for a home care organization.

C(I) NEED

C(I).1. DESCRIBE THE RELATIONSHIP OF THIS PROPOSAL TO THE IMPLEMENTATION OF THE STATE HEALTH PLAN AND TENNESSEE'S HEALTH: GUIDELINES FOR GROWTH.

A. PLEASE PROVIDE A RESPONSE TO EACH CRITERION AND STANDARD IN CON CATEGORIES THAT ARE APPLICABLE TO THE PROPOSED PROJECT. DO NOT PROVIDE RESPONSES TO GENERAL CRITERIA AND STANDARDS (PAGES 6-9) HERE.

B. APPLICATIONS THAT INCLUDE A CHANGE OF SITE FOR A HEALTH CARE INSTITUTION, PROVIDE A RESPONSE TO GENERAL CRITERION AND STANDARDS (4)(a-c).

Project-Specific Review Criteria: PET Scanners

The State Health Plan contains CON review criteria for PET scanners. The applicant believes that they were intended primarily to guide review of proposed new PET units in a service area, i.e., projects in which an additional PET is proposed for an area, or in which a prior approved PET is proposing a relocation that will result in a new service area.

Neither factor is present in this project. This project is to relocate an existing cardiac PET system under new ownership, not to add a system to the area. The relocation is within the same county. At the applicant's practice, the cardiac PET will serve only counties that are already being served by the current provider of the service. That current provider has requested that the practice take over the service. Therefore, applying "need" criteria as if this service did not already exist, or would be duplicative, does not seem logical. This is only a change of provider of an existing service, with a simultaneous relocation to a premises already approved for the service's current owner. The applicant therefore asks that the criteria be applied prudently.

Following this page is a copy of the PET Standards and Criteria from the 2009 State Health Plan. Following that document are the applicant's responses to those criteria, numbered to correspond to the State Health Plan document.

APPENDIX A. Revised and Updated Standards and Criteria for Positron Emission Tomography (PET) services



STATE OF TENNESSEE

**STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR**

POSITRON EMISSION TOMOGRAPHY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Positron Emission Tomography (PET) services. Existing providers of PET services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for PET services.

These standards and criteria are effective immediately as of November 18, 2009, the date of approval and adoption by the governor of the State Health Plan. Applications to provide PET services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Positron Emission Tomography (PET): A noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body (source: The Centers for Medicare and Medicaid Services). PET differs from other nuclear medicine modalities in the type of radiation emitted and in the type of scanner required to detect it. By measuring the distributions of certain radiotracers in the body some time after they have been administered, PET can be used to diagnose physical abnormalities and to study body functions in normal subjects.

PET Unit: Diagnostic equipment (often referred to as a "scanner") that uses a positron camera (tomograph) to produce cross-sectional tomographic images (this process is often referred to as a "scan"). The images are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-(F-18) Fluoro-D-Glucose (FDG) which are administered intravenously to the patient. The radioactive tracers may be

produced on-site, e.g. with a cyclotron, or may be ordered from commercial distributors. As a result, factors such as equipment cost, geographic distribution and availability of distributors, and other related factors (regulatory compliance/certification) should be considered by the Agency in its review of all PET applications.

First developed in the 1970s, initial PET scanners were dedicated machines performing only that service. PET scanners can be either fixed (stationary) or mobile. Current technological adaptations include hybrid machines, such as combined PET-CT (computed tomography) scanners that are capable of performing a variety of nuclear medicine studies.

PET Procedure: A PET diagnostic scan or combination of scans performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition.

Stationary PET Unit: A non-moveable PET unit housed at a single permanent location.

Mobile PET Unit: A PET unit and transporting equipment that is moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the Continental United States.

Capacity: The measure of the maximum number of PET scans per PET unit per year based upon the type of PET equipment to be used (i.e., stationary or mobile).

Stationary PET Unit Capacity: Total capacity of a stationary PET unit is 2,000 procedures per year and is based upon a daily operating efficiency of eight procedures per day x 250 days of operation per year. The optimal efficiency for a stationary PET unit is 80 percent of total capacity, or 1,600 procedures per year.

Mobile PET Unit Capacity: Total capacity of a mobile PET scanner is 400 annual procedures per day of operation per week and is based upon a daily operating efficiency of at least eight (8) procedures per day x number of days in operation per week x approximately 50 weeks per year. The optimal efficiency of a mobile PET unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 320 procedures per year, or 80 percent of total capacity.

PET Unit Service Area: The counties, or portions thereof, representing a reasonable area in which a health care institution intends to provide PET unit services, including, but not limited to, oncology and cardiology diagnostic and treatment services, and in which at least 75% of its service recipients reside. A PET unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of PET units needed in a given service area. The estimate is based upon an optimal efficiency of 1,600 procedures per year for a stationary PET unit and an optimal efficiency of 320 annual procedures per day of operation per week for a mobile PET unit, and the quantitative estimate of the number

of patients who potentially could benefit from PET diagnostic services, especially those patients pertaining to the following categories:

- those patients where the use of PET unit services is essential to the diagnosis, treatment, or surveillance of cancer, including, but not limited to, diagnosis codes approved by the Centers for Medicare and Medicaid Services (CMS);
- those patients who are either non-emergent candidates for open heart surgery or therapeutic cardiac catheterization procedures;
- those patients with a diagnosis of partial complex epilepsy for whom surgical intervention is being considered; and
- any other patient population that may benefit from the accessibility to stationary or mobile PET unit services as a result of expanded clinical applications and changes in the reimbursement of PET service by third party payors, including those pertaining to programs administered by the CMS.

In addition to the above determinants of service area capacity, applicants should consider demographic patterns, including the results of estimates of population health risk factors and population-based cancer, heart disease, or other applicable clinical incidence rates. The data should be consistent with data prepared by the Tennessee Department of Health. Applicants should also document the extent, if any, of diagnostic oncology, cardiac and neurological medical services in the proposed service area in its determination of the need for PET unit services.

Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed

service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.
4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.
5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.
 - b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.
 - c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

- d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.
 - e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.
 - f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.
7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.
8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;
 - c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

- d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

APPLICANT'S RESPONSES TO THE CRITERIA

Note: For brevity, the CON PET criteria in the preceding section are paraphrased below in bold letters. The applicant has added sub-parts "A", "B", etc. to the numbered State Plan criteria when responding to multiple paragraphs of some criteria.

1A. For a "new stationary PET unit", projected annual utilization should be a minimum of 1,000 procedures in Year One and a minimum of 1,600 procedures every year thereafter.

Response: This criterion is not applicable, because this is not a new unit for the area. It is a proposed change of provider/owner for an existing, previously approved cardiac PET unit and service. Its use will be restricted to cardiac procedures, for the patients of a single practice. It is not ever likely to perform the minimum numbers of procedures recommended for a general PET unit without such restrictions. If it continues to grow at 10% a year, it will reach a rate of 1,600 annual procedures in CY2024, its tenth year of operation.

IB. Demographic Data--An application for a stationary unit should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

Response: This is not applicable, because it is part of criterion #1 for "applicants proposing a new stationary PET unit..." or "a mobile PET unit", neither of which is proposed in this application. However, in the Frequent Charge chart in this application, the applicant's utilization by ICD-9 is projected for CY2015 and CY2016. Ample demographic information on the service area is presented. However, the service's utilization has not been projected by population-based factors, but rather from trending past increases in demand for the service within the medical practice which seeks to offer the service.

2A. Applicants "applying for a proposed new PET unit" should document its accessibility to 75% of the service area population.

Response: Not applicable because a new PET unit is not being proposed. However, the project is very accessible to 75% of the service area population. Approximately 85.3% of its patients will come from the primary service area of Washington, Carter, and Unicoi Counties. The principal communities in all three of those counties are less than thirty minutes' average drive time of Karing Hearts Cardiology, the project site. See Table Four in the application.

2B. Identify PET unit locations, capacity, and utilization in non-Tennessee counties in the service area, and discuss project impact on them.

Response: Not applicable because a new PET unit is not being proposed, and also because there are no non-Tennessee counties in the primary service area.

3. Document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: There is no other cardiac PET provider in the primary service area, with whom the applicant could share this service. The only other cardiac PET unit in the region is the Wellmont Health System in Kingsport, in adjoining Sullivan County. It is not as physically close to primary service area residents as Gray or Johnson City. It is not available to patients who are not in the practice of Wellmont Cardiology Services. It is also going to be used at full capacity by patients of Wellmont Cardiology, within three years. So alternate services in the region are not as accessible or available. They are likely to be comparable in terms of continuity, cost, and quality of care, for most referred patients.

4. (This criterion is not applicable because it pertains only to a proposed new mobile PET.)

5A. Need for “one additional stationary PET unit in an area” is likely if the utilization of existing PET providers was at or above 80% of their total capacity (i.e., at or above 1,600 procedures annually), as reported to HSDA most recently.

Response: Not applicable. The applicant is not proposing to open an additional PET unit in the area. The applicant’s medical practice is proposing to acquire and operate the only PET service currently approved within in the Karing Hearts Cardiology primary service area.

In Section C(I)5 of this application, the applicant provides historic utilization for the ODC in Gray (Washington County), which provides the only such service in the primary service area. It attained 668 procedures in CY2012. The section also provides the PET utilization of all PET providers in or near the Tennessee primary service area. Only one has reported to the HSDA an annual utilization of 1,600 or more procedures.

5B. Applicants (for “one additional stationary unit in a service area”) should perform at least 1,000 and 1,600 procedures per year in the first two years, respectively.

Response: This criterion is not applicable, because this is not an additional unit for the area. It is a proposed change of provider/owner for an existing, previously approved cardiac PET unit and service. Its use will be restricted to cardiac procedures, for the patients of a single practice. If it achieves an annual growth rate of 10% a year, it will reach a rate of 1,600 annual procedures in CY2024, its tenth year of operation.

6a. The PET unit must be FDA-certified for clinical use.

Response: Complies; documentation is provided in the Attachments.

6b. The PET's physical environment must conform to applicable Federal standards, manufacturer's specifications, and licensing requirements.

Response: Compliance in this regard is established by the architect's letter attesting to intended compliance with applicable codes, standards, and licensing requirements.

6c. The applicant should demonstrate how emergencies will be managed in conformity with accepted medical practice.

Response: Please see the applicant's emergency response protocols, in the Attachments.

6d. The applicant should establish protocols assuring that procedures are medically necessary and are not unnecessarily duplicative.

Response: Please see the applicant's medical necessity protocols, in the Attachments.

6e. Medical Direction should be provided by a licensed physician Board certified in either Nuclear Medicine or Diagnostic Radiology. Licensure should be in place for handling radioactive pharmaceuticals and medical isotopes. Interpreting physicians should have documented experience and training, credentialing, and/or Board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Response: Dr. Jeffrey Schoondyke, whose C.V. is in the Attachments, is a Board certified cardiologist who has been Medical Director for the cardiac PET service at the Gray ODC for several years. He is trained and highly experienced in the use and interpretation of cardiac PET studies. Dr. Schoondyke will continue to be Medical Director of the cardiac PET service when it moves to his practice office in Johnson City. His practice already holds a license for handling radioactive substances, for nuclear medicine studies of other types that the practice currently performs.

6f. Applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. The medical director should be an active member of the medical staff of the hospital with which the agreement is made.

Response: Dr. Jeffrey Schoondyke is an active member of the medical staff of Johnson City Medical Center, with which Karing Hearts Cardiology will have a transfer agreement if this project is approved.

7. Submission of data to the HSDA

Response: The applicant commits to comply with the requirement for timely submission of the identified data to the HSDA Equipment Registry.

Factors for Special Consideration

8a. Service to Medically Underserved Areas

Response: In the Attachments, the applicant has included documentation of the underserved areas in the primary service area.

8b. Higher than Average State Rate of Heart Disease

Response: The applicant is not claiming this special circumstance at this time. This is neither a new service for the area, nor an additional unit for the area; so justification of this type should not be deemed necessary.

8c. Safety Net Hospital; Children's Hospital; or Comprehensive Cancer Program

Response: The application is not by a safety net hospital, a children's hospital, or a hospital with a comprehensive cancer program.

8d. Commitment to Contract with One or More TennCare MCO's and to participate in Medicare.

Response: The payor mix of Dr. Schoondyke's practice, from which the cardiac PET's referrals will come, is currently approximately 60% Medicare and 6% TennCare. His practice contracts with all available MCO's in the area.

The Framework for Tennessee's Comprehensive State Health Plan

Five Principles for Achieving Better Health

The following Five Principles for Achieving Better Health serve as the basic framework for the State Health Plan. After each principle, the applicant states how this CON application supports the principle, if applicable.

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans.

Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

This project reflects a collaboration between Karing Hearts Cardiology and Molecular Imaging Alliance ODC in Gray (which is going to close in the near future), to find a way to continue offering cardiac PET services to the Johnson City area and to the primary service area now being served. Approving Karing Hearts Cardiology as the successor to Molecular in this service will ensure its continued availability. Relocating Molecular's remaining cardiac PET unit to Johnson City, closer to physicians and patients who utilize it, will greatly improve access to this testing modality, which in turn will increase its utilization, providing improved diagnostic information and significant cost savings in terms of subsequent interventional care.

2. Access to Care

Every citizen should have reasonable access to health care.

Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

Geography has been a barrier to optimal use of the cardiac PET scanning systems at the ODC in Gray. The service is located miles outside the medical centers of the service area, making it less accessible for patients and physicians and limiting its use. This project will address that issue, improving access for patients who live in this sector of Upper East Tennessee and seek healthcare in Johnson City.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the

continued development of the state's health care system. The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.

This is an opportunity for the State regulatory system to assist providers in making a needed service more accessible, so that its technology can be more completely and efficiently utilized.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and that standards are adhered to by health care providers. Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.

The project will bring this modality much closer to its current and potential users (cardiologists and their patients in Johnson City). That will make it more readily and efficiently accessible. The applicant believes that increased accessibility to cardiac PET scanning will increase its use, leading to better diagnostic data, which can improve diagnosis and intervention for this large group of patients.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

The project is neutral with respect to training of health professionals. It is not a training/rotation site for any schools at the present time. The applicant would welcome such an affiliation, should it be offered.

C(I).2. DESCRIBE THE RELATIONSHIP OF THIS PROJECT TO THE APPLICANT'S LONG-RANGE DEVELOPMENT PLANS, IF ANY.

The applicant is a private physician practice that does not prepare formal long-range development plans.

C(I).3. IDENTIFY THE PROPOSED SERVICE AREA AND JUSTIFY THE REASONABLENESS OF THAT PROPOSED AREA. SUBMIT A COUNTY-LEVEL MAP INCLUDING THE STATE OF TENNESSEE CLEARLY MARKED TO REFLECT THE SERVICE AREA. PLEASE SUBMIT THE MAP ON A 8-1/2" X 11" SHEET OF WHITE PAPER MARKED ONLY WITH INK DETECTABLE BY A STANDARD PHOTOCOPIER (I.E., NO HIGHLIGHTERS, PENCILS, ETC.).

A service area map and a map showing the location of the service within the State of Tennessee are provided as Attachments C, Need--3 at the back of the application.

The cardiac PET service area, under the control of Karing Hearts Cardiology, will continue to be most of the counties around Johnson City that are now being served by the Gray ODC. Table Five on the next page shows Karing Heart's current primary service area counties for referrals to cardiac PET. They have generated, and will continue to generate, approximately 85% of the practice's cardiac PET referrals.

Within the primary service area, approximately 58.2% of the practice's YTD2013 referrals to cardiac PET were residents of Washington County, where the service will continue to be located if this application is approved. Another 27.1% of its cardiac PET referrals were residents of adjoining Carter and Unicoi Counties.

Karing Heart's secondary service area for this type of patient, contributing 14.7% of the practice's cardiac PET referrals, includes Sullivan, Greene, Johnson, Hawkins, and Grainger Counties, and unidentified counties in nearby areas of Virginia and North Carolina.

Table Five: Patient Origin
Karing Heart Cardiology Referrals for Cardiac PET Scans
CY2013 / CY2015-CY2016

County	Karing Heart Referrals for Cardiac PET, Jan-Oct 2013	Percent of Total	Cumulative Percent of Total	Year One CY2015 Cardiac PET Scans	Year Two CY2016 Cardiac PET Scans
<i>Primary Service Area (PSA) Counties</i>					
Washington	221	58.2%	58.2%	394.3	433.3
Carter	73	19.2%	77.4%	130.2	143.1
Unicoi	30	7.9%	85.3%	53.5	58.8
<i>PSA Subtotal</i>	324	85.3%		578.1	635.2
<i>Secondary Service Area (SSA) Counties and States</i>					
Sullivan	24	6.3%	91.6%	42.8	47.1
Greene	9	2.4%	93.9%	16.1	17.6
Johnson, Hawkins, Grainger	11	2.9%	96.8%	19.6	21.6
Other States	12	3.2%	100.0%	21.4	23.5
<i>SSA Subtotal</i>	56	14.7%		99.9	109.8
<i>Grand Total</i>	380	100.0%		678.0	745.0

Source: Cardiac PET scan patient origin from practice records; projections by practice management.

Note: Scans calculated to tenths to document round numbers of Years One and Two total utilization projections.

C(I).4.A DESCRIBE THE DEMOGRAPHICS OF THE POPULATION TO BE SERVED BY THIS PROPOSAL.

Table Six, following this page, provides the demographic profile for the three Tennessee counties in this project's primary service area. Basically, area residents are somewhat older and lower income than the State average.

The counties in the primary service area (all in Tennessee) have a median age of 42.1 compared to the State median age of 38.0; and 17.0% of area residents are elderly compared to 14.6% Statewide. In addition, the service area's elderly population is projected to increase 4.4% in size over the next four years. The aging of the population will continue to increase the need for high-quality, accessible, affordable cardiac care in this area. This project helps meet all three needs.

Also, the service area's median income of \$36,505 is 17% below the State average. But a smaller percent of service area residents (12.0%) are below the poverty level than in Tennessee as a whole (16.9%). The service area's TennCare population is 16.5% of all residents, compared to 18.3% Statewide. The project will be accessible to low-income residents of the service area. Approximately 66% of patients served by the project will be Medicare or Medicaid/TennCare enrollees (60% Medicare; 6% TennCare).

**Table Six: Demographic Characteristics of Primary Service Area Counties
Karing Hearts Cardiology's Cardiac PET Service
2013-2017**

Demographic	Washington County	Carter County	Unicoi County	PRIMARY SERVICE AREA	STATE OF TENNESSEE
Median Age-2010 US Census	39.3	42.2	44.9	42.1	38.0
Total Population-2013	128,537	57,228	18,334	204,099	6,528,014
Total Population-2017	136,509	57,548	18,487	212,544	6,772,022
Total Population-% Change 2013 to 2017	6.2%	0.6%	0.8%	4.1%	3.7%
Age 65+ Population-2013	21,028	10,710	3,015	34,753	950,177
% of Total Population	16.4%	18.7%	16.4%	17.0%	14.6%
Age 65+ Population-2017	21,430	10,978	3,874	36,282	1,072,143
% of Population	15.7%	19.1%	21.0%	17.1%	15.8%
Age 65+ Population- % Change 2013-2017	1.9%	2.5%	28.5%	4.4%	12.8%
Median Household Income	\$42,104	\$32,148	\$35,265	\$36,506	\$43,989
TennCare Enrollees (7/13)	19,004	11,262	3,505	33,771	1,193,721
Percent of 2013 Population Enrolled in TennCare	14.8%	19.7%	19.1%	16.5%	18.3%
Persons Below Poverty Level (2013)	22,237	12,590	3,795	38,622	1,103,234
Persons Below Poverty Level As % of Population (US Census)	17.3%	22.0%	20.7%	12.0%	16.9%

Sources: TDH Population Projections, 2013; U.S. Census QuickFacts;
TennCare Bureau. PSA data is unweighted average or total of county data.
NR means not reported in U.S. Census source document.

C(I).4.B. DESCRIBE THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION, INCLUDING HEALTH DISPARITIES, THE ACCESSIBILITY TO CONSUMERS, PARTICULARLY THE ELDERLY, WOMEN, RACIAL AND ETHNIC MINORITIES, AND LOW-INCOME GROUPS. DOCUMENT HOW THE BUSINESS PLANS OF THE FACILITY WILL TAKE INTO CONSIDERATION THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION.

The applicant's practice had demonstrated accessibility to these consumer groups. More than half (60%) of Karing Hearts Cardiology's patients YTD were Medicare and another 6% were TennCare/Medicaid. The practice will continue to be accessible to these groups. The projected charity care for the cardiac PET service is 3% of gross charges. The practice's current management works with each patient to pay as he or she is able.

C(I).5. DESCRIBE THE EXISTING OR CERTIFIED SERVICES, INCLUDING APPROVED BUT UNIMPLEMENTED CON'S, OF SIMILAR INSTITUTIONS IN THE SERVICE AREA. INCLUDE UTILIZATION AND/OR OCCUPANCY TRENDS FOR EACH OF THE MOST RECENT THREE YEARS OF DATA AVAILABLE FOR THIS TYPE OF PROJECT. BE CERTAIN TO LIST EACH INSTITUTION AND ITS UTILIZATION AND/OR OCCUPANCY INDIVIDUALLY. INPATIENT BED PROJECTS MUST INCLUDE THE FOLLOWING DATA: ADMISSIONS OR DISCHARGES, PATIENT DAYS, AND OCCUPANCY. OTHER PROJECTS SHOULD USE THE MOST APPROPRIATE MEASURES, E.G., CASES, PROCEDURES, VISITS, ADMISSIONS, ETC.

The only cardiac PET service in the primary service area of Karing Hearts Cardiology is the ODC service in Gray, that this application seeks to acquire and convert to a practice-based service.

Table Seven below shows that ODC's historic utilization from 2009 to 2012. Its growth has been exceptionally strong despite its remote location midway between the region's two largest medical care centers. Over the period 2009-2012, utilization of the service increased more than 17% per year (compound annual growth rate or CAGR).

Table Seven: Utilization of Molecular Imaging Alliance Cardiac PET 2009-2012				
	2009	2010	2011	2012
Procedures	411	342	514	668
% Annual Change	--	- 16.8%	+50.3%	+30.0%
Numeric Annual Change	--	-69	+172	+154
% Change 2009-2012	--	--	--	+62.5%
Numeric Change 2009-12	--	--	--	+257
Compound Annual Growth Rate 2009-2012	--	--	--	>17%

Source: HSDA Registry 2009-11; Molecular Imaging Alliance records, 2012.

The following page provides the HSDA Registry's data for all PET units in the primary and secondary service area--only one of which (LifeScan, dba Molecular Imaging Associates) is equipment dedicated to cardiac PET. To the applicant's best knowledge, only one other PET in this area is even able to perform cardiac PET studies--the mobile PET operated by Holston Valley Medical Center. However, its first priority is to meet high demand for oncology PET scans; Wellmont Cardiology Service's recently approved application for Cardiac PET stated that the mobile unit limits cardiac studies to only 300 patients per year.

Health Care Providers that Utilize PET Scanners

County	Provider Type	Provider	Year	Number of	Mobile ?	Mobile Days Used	Total Procedures	Total Gross Charges	Average Gross Charge
Greene	HOSP	Laughlin Memorial Hospital, Inc.	2009	1	Mobile (Part)	1 day/week	436	\$1,375,036.00	\$3,153.75
Greene	HOSP	Laughlin Memorial Hospital, Inc.	2010	1	Mobile (Part)	2 days/week	456	\$1,928,760.00	\$4,229.74
Greene	HOSP	Laughlin Memorial Hospital, Inc.	2011	1	Mobile (Part)	2 days/week	430	\$1,815,432.00	\$4,221.93
Greene	HOSP	Laughlin Memorial Hospital, Inc.	2012	1	Mobile (Part)	1 day/week	351	\$1,483,770.00	\$4,227.26
Hamblen	HOSP	Morristown-Hamblen Hospital	2009	1	Mobile (Part)	2 days/week	341	\$1,534,500.00	\$4,500.00
Hamblen	HOSP	Morristown-Hamblen Hospital	2010	1	Mobile (Part)	3 days/week	296	\$987,000.00	\$3,334.46
Hamblen	HOSP	Morristown-Hamblen Hospital	2011	1	Mobile (Part)	2 days/week	317	\$1,313,875.00	\$4,144.72
Hamblen	HOSP	Morristown-Hamblen Hospital	2012	1	Mobile (Part)	2 days/week	405	\$1,808,573.00	\$4,465.61
Sullivan	HOSP	Bristol Regional Medical Center	2009	1	Mobile (Part)	2 days/week	464	\$2,067,596.00	\$4,456.03
Sullivan	HOSP	Bristol Regional Medical Center	2010	1	Mobile (Part)	2 days/week	435	\$1,840,351.00	\$4,230.69
Sullivan	HOSP	Bristol Regional Medical Center	2011	1	Mobile (Part)	2 days/week	466	\$2,080,050.00	\$4,463.63
Sullivan	HOSP	Bristol Regional Medical Center	2012	1	Mobile (Part)	2 days/week	460	\$2,105,911.00	\$4,578.07
Sullivan	HOSP	Holston Valley Medical Center	2009	1	Mobile (Part)	3 days/week	1263	\$5,626,711.00	\$4,455.04
Sullivan	HOSP	Holston Valley Medical Center	2010	1	Mobile (Part)	3 days/week	1381	\$6,154,683.00	\$4,456.69
Sullivan	HOSP	Holston Valley Medical Center	2011	1	Mobile (Part)	3 days/week	1501	\$6,636,461.00	\$4,421.36
Sullivan	HOSP	Holston Valley Medical Center	2012	1	Mobile (Part)	3 days/week	1677	\$7,542,662.00	\$4,497.71
Sullivan	HOSP	Indian Path Medical Center	2009	1	Mobile (Part)	1 day/week	138	\$931,955.00	\$6,753.30
Sullivan	HOSP	Indian Path Medical Center	2010	1	Mobile (Part)	1 day/week	154	\$1,061,218.00	\$6,891.03
Sullivan	HOSP	Indian Path Medical Center	2011	1	Mobile (Part)	1 day/week	133	\$1,000,842.00	\$7,525.13
Sullivan	HOSP	Indian Path Medical Center	2012	1	Mobile (Part)	1 day/week	143	\$1,202,291.00	\$8,407.63
Washington	HOSP	Johnson City Medical Center	2009	1	Fixed	0	2121	\$14,209,376.00	\$6,699.38
Washington	HOSP	Johnson City Medical Center	2010	1	Fixed	0	1769	\$12,136,169.00	\$6,860.47
Washington	HOSP	Johnson City Medical Center	2011	1	Fixed	0	1542	\$11,506,728.00	\$7,462.21
Washington	HOSP	Johnson City Medical Center	2012	1	Fixed	0	1234	\$10,275,190.00	\$8,326.73
Washington	ODC	LifeScan Tennessee, LLC	2009	2	Fixed	0	411	\$1,336,879.00	\$3,252.75
Washington	ODC	LifeScan Tennessee, LLC	2010	2	Fixed	0	342	\$587,344.00	\$1,717.38
Washington	ODC	LifeScan Tennessee, LLC	2011	2	Fixed	0	514	\$1,623,309.46	\$3,158.19
Washington	ODC	LifeScan Tennessee, LLC	2012	2	Fixed	0	623	\$1,139,661.00	\$1,829.31
2009 Service Area Total								\$27,082,053.00	\$5,234.26
2010 Service Area Total								\$24,695,525.00	\$5,109.77
2011 Service Area Total								\$25,976,697.46	\$5,298.12
2012 Service Area Total								\$25,558,058.00	\$5,223.39

C(I).6. PROVIDE APPLICABLE UTILIZATION AND/OR OCCUPANCY STATISTICS FOR YOUR INSTITUTION FOR EACH OF THE PAST THREE (3) YEARS AND THE PROJECTED ANNUAL UTILIZATION FOR EACH OF THE TWO (2) YEARS FOLLOWING COMPLETION OF THE PROJECT. ADDITIONALLY, PROVIDE THE DETAILS REGARDING THE METHODOLOGY USED TO PROJECT UTILIZATION. THE METHODOLOGY MUST INCLUDE DETAILED CALCULATIONS OR DOCUMENTATION FROM REFERRAL SOURCES, AND IDENTIFICATION OF ALL ASSUMPTIONS.

This application is for a new service for the applicant's medical practice, so there is no historical utilization at this location for the practice per se. However, Karing Hearts Cardiology has been the major referral source for the service at its Gray facility; and the practice's principal physician, Dr. Schoondyke, is the ODC's Medical Director for the service. Therefore, the ODC's historical utilization is shown in Section C(I)5 above.

Future utilization for the cardiac PET as a practice-based service has been projected very conservatively, assuming utilization only by Drs. Schoondyke and Davidson, the two cardiologists of the practice. The projection is shown in Table Eight below. The methodology was as follows.

Dr. Schoondyke made 380 referrals to the Gray ODC, for cardiac PET studies from January through October 2013. This annualizes to a projection of 456 annual referrals ($380 \times 12/10 = 456$) for CY2013. The practice has just added Dr. Davidson, who brings an established patient base to the practice, and it is projected that her new patients will increase referrals for cardiac PET by a minimum of 25% in her first year of practice. In addition, despite the service's current inconvenient location, the area demand for cardiac PET tests at Gray has been growing at a rate of 17% a year. So it is reasonable to expect an additional annual increase of 10%, for Dr. Schoondyke's own referrals, from CY2013 to CY2014. The 10% annual increase, plus the one-time 25% increase from Dr. Davidson's patients, will result in a 35% increase of referrals in CY2014--or a total of 616 PET referrals. After 2014, with the service relocated into the Karing Hearts practice office, the applicant expects continuing 10% annual growth, resulting in 678 and 745 cardiac PET studies in Years One and Two of the project.

Table Eight: Projected Referrals for Cardiac PET at Karing Hearts Cardiology 2012-2015				
	CY2013	CY2014	Yr 1-CY2015	Yr 2-CY2016
Procedures	456	616	678	745
Annual Change	--	+35%	+10%	+10%

Source: Practice management.

The cardiac PET's utilization, even at its present inconvenient location, has been increasing at an average rate of 17% since 2009. The projection in Table Eight assumes an average annual increase of only 96.3 referrals a year over the three-year projection period. The applicant considers this projection methodology to be conservative, for several reasons: (a) there is increasing documentation of the clinical benefits of converting most SPECT studies to cardiac PET studies; (b) the cardiac PET will be at a location much more convenient for most service area patients; and (c) providers and insurers will want to achieve the cost savings associated with cardiac PET's ability to rule out the need for some patients to undergo coronary artery bypass surgery.

C(II)1. PROVIDE THE COST OF THE PROJECT BY COMPLETING THE PROJECT COSTS CHART ON THE FOLLOWING PAGE. JUSTIFY THE COST OF THE PROJECT.

- **ALL PROJECTS SHOULD HAVE A PROJECT COST OF AT LEAST \$3,000 ON LINE F (MINIMUM CON FILING FEE). CON FILING FEE SHOULD BE CALCULATED ON LINE D.**

- **THE COST OF ANY LEASE (BUILDING, LAND, AND/OR EQUIPMENT) SHOULD BE BASED ON FAIR MARKET VALUE OR THE TOTAL AMOUNT OF THE LEASE PAYMENTS OVER THE INITIAL TERM OF THE LEASE, WHICHEVER IS GREATER. NOTE: THIS APPLIES TO ALL EQUIPMENT LEASES INCLUDING BY PROCEDURE OR "PER CLICK" ARRANGEMENTS. THE METHODOLOGY USED TO DETERMINE THE TOTAL LEASE COST FOR A "PER CLICK" ARRANGEMENT MUST INCLUDE, AT A MINIMUM, THE PROJECTED PROCEDURES, THE "PER CLICK" RATE AND THE TERM OF THE LEASE.**

- **THE COST FOR FIXED AND MOVEABLE EQUIPMENT INCLUDES, BUT IS NOT NECESSARILY LIMITED TO, MAINTENANCE AGREEMENTS COVERING THE EXPECTED USEFUL LIFE OF THE EQUIPMENT; FEDERAL, STATE, AND LOCAL TAXES AND OTHER GOVERNMENT ASSESSMENTS; AND INSTALLATION CHARGES, EXCLUDING CAPITAL EXPENDITURES FOR PHYSICAL PLANT RENOVATION OR IN-WALL SHIELDING, WHICH SHOULD BE INCLUDED UNDER CONSTRUCTION COSTS OR INCORPORATED IN A FACILITY LEASE.**

- **FOR PROJECTS THAT INCLUDE NEW CONSTRUCTION, MODIFICATION, AND/OR RENOVATION; DOCUMENTATION MUST BE PROVIDED FROM A CONTRACTOR AND/OR ARCHITECT THAT SUPPORT THE ESTIMATED CONSTRUCTION COSTS.**

The architect's letter supporting the construction cost estimate is provided in Attachment C, Economic Feasibility--1.

On the Project Costs Chart, following this response:

Line A.1, A&E fees, were estimated by the project architect.

Line A.2, legal, administrative, and consultant fees, include costs for the CON process and legal services during project planning.

Line A.5, construction cost, was estimated by the project architect at no more than \$100,000, for renovation (including shielding) of 905 SF of medical office space.

Line A.6, contingency, was estimated by the architect at 5% of construction cost.

Line A.7 includes for fixed and moveable equipment indicates no costs because this project will relocate an entire cardiac PET system and all related equipment and room furnishings to the new site.

Line A.9 includes such costs as miscellaneous minor equipment and furnishings, and moving expenses.

Line B.1, \$109,035, is the fair market value of the facility being leased, calculated in the two alternative ways required by staff rules. The pro rata market value of the space in the building exceeded the lease outlay, and was entered in this line of the Project Cost Chart as required by staff rules.

Lease Outlay Method:

5 years first lease term X 905 SF X \$12.00 PSF rate = \$54,300
lease outlay over first term.

Pro Rata Building Value Method:

905 SF project / 23,000 SF total building X \$2,771,044 actual CY2013 sale price
of the building = \$109,035 pro rata value of the space to be leased

The applicant again notes that this is a theoretical calculation of lease outlay required by HSDA staff rules. The project is to be placed in space already leased to the medical practice, and about half of that space will be shared with other types of patients. The project will impose no additional lease costs on the practice.

PROJECT COSTS CHART--KARING HEARTS CARDIAC PET SERVICE

A. Construction and equipment acquired by purchase:

1. Architectural and Engineering Fees	\$ 10,000
2. Legal, Administrative, Consultant Fees (Excl CON Filing)	15,000
3. Acquisition of Site	0
4. Preparation of Site	0
5. Construction Cost	100,000
6. Contingency Fund	5,000
7. Fixed Equipment (Not included in Construction Contract)	0
8. Moveable Equipment (List all equipment over \$50,000)	0
9. Other (Specify) <u>moving expenses</u>	1,500
<u>misc. office equipment & furnishings</u>	1,500

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land)	0
2. Building only <u>FMV of space being used for PET</u>	109,035
3. Land only	0
4. Equipment (Specify) <u>lease of Cardiac PET system</u>	144,000
5. Other (Specify) _____	0

C. Financing Costs and Fees:

1. Interim Financing <u>\$136,000 X 5% X .5 X .75 yrs</u>	2,550
2. Underwriting Costs	0
3. Reserve for One Year's Debt Service	0
4. Other (Specify) _____	0

D. Estimated Project Cost (A+B+C)

388,585

E. CON Filing Fee

3,000

F. Total Estimated Project Cost (D+E)

TOTAL \$ 391,585

Actual Capital Cost 138,550
Section B FMV 253,035

C(II).2. IDENTIFY THE FUNDING SOURCES FOR THIS PROJECT.

a. PLEASE CHECK THE APPLICABLE ITEM(S) BELOW AND BRIEFLY SUMMARIZE HOW THE PROJECT WILL BE FINANCED. (DOCUMENTATION FOR THE TYPE OF FUNDING MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND IDENTIFIED AS ATTACHMENT C, ECONOMIC FEASIBILITY--2).

 x **A. Commercial Loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;**

 B. Tax-Exempt Bonds--copy of preliminary resolution or a letter from the issuing authority, stating favorable contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;

 C. General Obligation Bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting;

 D. Grants--Notification of Intent form for grant application or notice of grant award;

 **E. Cash Reserves--Appropriate documentation from Chief Financial Officer;
or**

 F. Other--Identify and document funding from all sources.

The applicant has arranged for bank loan financing for the actual capital cost of the project (approximately \$139,000). Documentation of financing is provided in Attachment C, Economic Feasibility--2.

C(II).3. DISCUSS AND DOCUMENT THE REASONABLENESS OF THE PROPOSED PROJECT COSTS. IF APPLICABLE, COMPARE THE COST PER SQUARE FOOT OF CONSTRUCTION TO SIMILAR PROJECTS RECENTLY APPROVED BY THE HSDA.

This project requires only renovation of existing space, at an overall average cost of only \$110.50 PSF. The tables below, repeated from an earlier section of this application, compare that to renovation costs for the other two approved cardiac PET CON's in this region, and for several approved ODC's.

ODC renovation projects completed in 2008-2012 ranged from \$52-\$196 PSF construction cost, according to data from the HSDA Registry. Although the HSDA Registry did not compile a similar table for 2010-2012 due to the small number of ODC projects (5) completed in 2012, the Registry has supplied construction cost data for several of those projects; see Table Three-B below. Karing Hearts Cardiology's projected renovation cost of \$110.50 PSF compares well to these projects' costs.

Table Three-A: Outpatient Diagnostic Center Construction Cost PSF Years: 2008-2010			
	Renovated Construction	New Construction	Total Construction
1 st Quartile	\$51.55/sq ft	none	\$51.55/sq ft
Median	\$122.15/sq ft	none	\$122.15/sq ft
3 rd Quartile	\$196.46/sq ft	none	\$196.46/sq ft

Source: HSDA Registry. CON approved applications for years 2008 through 2010

Table Three-B: Outpatient Diagnostic Center Construction Cost PSF Years: 2012			
CON	ODC / Provider	Renovation Area	Construction Cost / sq ft
CN1010-046	Murfreesboro Diagnostic Imaging	9,587 SF	\$122.15/sq ft
CN1010-047	Cleveland Imaging	911 SF	\$269.91/sq ft
CN1103-008	E. TN Community Open MRI	795 SF	\$160.38/sq ft
CN1110-039	St. Thomas OP Imaging	7,737 SF	\$159.69/ sq ft
CN1110-039	Wellmont Cardiology Services Cardiac PET, Kingsport	2,080 SF	\$250 PSF
CN1304-014	Molecular Imaging ODC	847 SF	\$177 PSF
This Project	Karing Hearts Cardiology	905 SF	\$110.50 PSF

Source: HSDA Registry. CON approved ODC projects involving only renovation.

C(II).4. COMPLETE HISTORICAL AND PROJECTED DATA CHARTS ON THE FOLLOWING TWO PAGES--DO NOT MODIFY THE CHARTS PROVIDED OR SUBMIT CHART SUBSTITUTIONS. HISTORICAL DATA CHART REPRESENTS REVENUE AND EXPENSE INFORMATION FOR THE LAST THREE (3) YEARS FOR WHICH COMPLETE DATA IS AVAILABLE FOR THE INSTITUTION. PROJECTED DATA CHART REQUESTS INFORMATION FOR THE TWO YEARS FOLLOWING COMPLETION OF THIS PROPOSAL. PROJECTED DATA CHART SHOULD INCLUDE REVENUE AND EXPENSE PROJECTIONS FOR THE PROPOSAL ONLY (I.E., IF THE APPLICATION IS FOR ADDITIONAL BEDS, INCLUDE ANTICIPATED REVENUE FROM THE PROPOSED BEDS ONLY, NOT FROM ALL BEDS IN THE FACILITY).

This is a proposed service for the medical practice, so it does not have an operating history as a practice-based service. See the following pages for a Projected Data Chart, with notes itemizing "Other" expenses.

PROJECTED DATA CHART— KARING HEARTS CARDIOLOGY CARDIAC PET SERVICE

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2015	CY 2016
	PATIENTS	678	745
	PROCEDURES	678	745
A.	Utilization Data		
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$	\$
2.	Outpatient Services	2,063,832	2,155,285
3.	Emergency Services		
4.	Other Operating Revenue (Specify) <u>See notes page</u>		
	Gross Operating Revenue	\$ 2,063,832	\$ 2,155,285
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ 866,809	\$ 905,220
2.	Provision for Charity Care (3%)	61,915	64,659
3.	Provisions for Bad Debt (1%)	20,638	21,553
	Total Deductions	\$ 949,363	\$ 991,431
	NET OPERATING REVENUE	\$ 1,114,469	\$ 1,163,854
D.	Operating Expenses		
1.	Salaries and Wages	\$ 107,500	\$ 110,725
2.	Physicians Salaries and Wages	225,000	231,750
3.	Supplies	425,106	467,115
4.	Taxes	3,343	3,492
5.	Depreciation	6,667	6,667
6.	Rent	10,860	10,860
7.	Interest, other than Capital	0	0
8.	Management Fees		
a.	Fees to Affiliates	0	0
b.	Fees to Non-Affiliates	0	0
9.	Other Expenses (Specify) <u>See notes page</u>	266,283	275,655
	<small>Dues, Utilities, Insurance, and Prop Taxes.</small>		
	Total Operating Expenses	\$ 1,044,759	\$ 1,106,263
E.	Other Revenue (Expenses) -- Net (Specify)	\$	\$
	NET OPERATING INCOME (LOSS)	\$ 69,710	\$ 57,591
F.	Capital Expenditures		
1.	Retirement of Principal	\$ 11,685	\$ 12,245
2.	Interest	5,857	5,297
	Total Capital Expenditures	\$ 17,542	\$ 17,542
	NET OPERATING INCOME (LOSS)		
	LESS CAPITAL EXPENDITURES	\$ 52,168	\$ 40,049

PROJECTED DATA CHART
NOTES TO OTHER EXPENSES (LINE D9)

		CY2014	CY2015
Employee benefits		10,750	11,073
Overhead salaries		35,816	36,890
General office supplies		3,348	3,438
Advertising Bus dev		2,500	2,500
Meals and Entertainment		1,755	1,808
Utilities		16,054	16,535
Service repairs		18,400	24,400
Insurance and Lice		2,495	2,569
Equip Lease		144,000	144,000
Billing fee	2.5%	27,862	29,096
Accounting		1,303	1,346
Legal		2,000	2,000
	TOTAL	266,283	275,655

Overhead Salaries
mngmnt 25000
Med records 4992
Admin coord 5824

Supples (D3) Summary

	678	745
N-13 = \$380	\$257,640	\$283,100
Lexi = \$232	\$157,296	\$172,840
General = \$15	\$10,170	\$11,175
	\$425,106	\$467,115

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

Table Nine: Average Charges, Deductions, and Net Charges Karing Hearts Cardiology Cardiac PET Service		
	CY2015	CY2016
Procedures & Patients	678	745
Average Gross Charge Per Procedure & Patient	\$3,044	\$2,893
Average Deduction Per Procedure & Patient	\$1,400	\$1,331
Average Net Charge (Net Operating Revenue) Per Procedure & Patient	\$1,644	\$1,562
Average Net Operating Income Per Procedure & Patient, After Capital Expenditures	\$103	\$77

C(II).6.A. PLEASE PROVIDE THE CURRENT AND PROPOSED CHARGE SCHEDULES FOR THE PROPOSAL. DISCUSS ANY ADJUSTMENT TO CURRENT CHARGES THAT WILL RESULT FROM THE IMPLEMENTATION OF THE PROPOSAL. ADDITIONALLY, DESCRIBE THE ANTICIPATED REVENUE FROM THE PROPOSED PROJECT AND THE IMPACT ON EXISTING PATIENT CHARGES.

For proposed charges, please see C(II).6.B below. Because this project is for a physician practice service, with a positive operating margin, there are no other types of charges that could be impacted by the project. The Projected Data Chart shows that the applicant will be maintaining approximately the same net operating revenue per procedure (amount actually received from payors after deductions) as the prior owner experienced. See Table Ten in response C(II).6.B below.

C(II).6.B. COMPARE THE PROPOSED CHARGES TO THOSE OF SIMILAR FACILITIES IN THE SERVICE AREA/ADJOINING SERVICE AREAS, OR TO PROPOSED CHARGES OF PROJECTS RECENTLY APPROVED BY THE HSDA. IF APPLICABLE, COMPARE THE PROJECTED CHARGES OF THE PROJECT TO THE CURRENT MEDICARE ALLOWABLE FEE SCHEDULE BY COMMON PROCEDURE TERMINOLOGY (CPT) CODE(S).

Table Ten below compares this project's projected charges to the recently approved projected charges of Wellmont Cardiac Services' cardiac PET service in Kingsport, and Molecular Imaging Alliance's approved CON application to relocate its Cardiac PET ODC to Johnson City.

The projected average gross charge for this ODC in 2014 in Johnson City is projected to be higher than at the Gray location in CY2012. However, the ODC's projected average net operating revenue (receipts), which is its impact on payors, will be lower.

Table Ten: Comparative Gross Charges Per Cardiac PET Scan	
Provider	Average Gross / Net Revenue
Molecular Imaging Alliance, Gray	Actual 2012: \$1,764 / \$1,764
Wellmont Cardiology Services at Kingsport	Proposed, CY2014: \$3,678 / \$1,140
Molecular Imaging Alliance, Johnson City	Proposed, CY2014: \$3,133 / \$1,675
Karing Hearts Cardiology, Johnson City	Proposed, CY2015: \$3,044 / \$1,644

Source: HSDA records; Applicant's Projected Data Chart, this application.

The following page contains Table Eleven, a chart showing the most frequent procedures to be performed, with their current Medicare reimbursement, and their projected Years One and Two utilization and average gross charges.

**Table Eleven: Karing Hearts Cardiology Cardiac PET Service
Charge Data for Most Frequently Performed Procedures**

SERVICE CARDIAC PET

CPT	Descriptor	Current Medicare Allowable	Average Gross Charge			Utilization		
			Current	Year 1	Year 2	Current	Year 1	Year 2
78492	PET MYOCARD PRF MUL RST/STRS	\$1,033	3,205.00	3,044.75	2,892.51	na	668	734
78459	PET MYOCARDIAL IMAGING	\$1,016	3,205.00	3,044.75	2,892.51	na	10	11
A9526	NITROGEN N-13 AMMONIA	*Invoice Total	380.00	380.00	380.00	na	678	745
J2785	LEXISCAN 0.1 MG	\$54	100.00	100.00	100.00	na	678	745

Source: Practice Management

C(II).7. DISCUSS HOW PROJECTED UTILIZATION RATES WILL BE SUFFICIENT TO MAINTAIN COST-EFFECTIVENESS.

The service is projected to operate with a positive cash flow and a rapid annual increase of utilization; its continued increases in utilization will be sufficient to ensure its long-term viability.

C(II).8. DISCUSS HOW FINANCIAL VIABILITY WILL BE ENSURED WITHIN TWO YEARS; AND DEMONSTRATE THE AVAILABILITY OF SUFFICIENT CASH FLOW UNTIL FINANCIAL VIABILITY IS MAINTAINED.

The applicant is an established medical practice with active reimbursement income, so addition of the service should not cause any cash flow issues.

C(II).9. DISCUSS THE PROJECT'S PARTICIPATION IN STATE AND FEDERAL REVENUE PROGRAMS, INCLUDING A DESCRIPTION OF THE EXTENT TO WHICH MEDICARE, TENNCARE/MEDICAID, AND MEDICALLY INDIGENT PATIENTS WILL BE SERVED BY THE PROJECT. IN ADDITION, REPORT THE ESTIMATED DOLLAR AMOUNT OF REVENUE AND PERCENTAGE OF TOTAL PROJECT REVENUE ANTICIPATED FROM EACH OF TENNCARE, MEDICARE, OR OTHER STATE AND FEDERAL SOURCES FOR THE PROPOSAL'S FIRST YEAR OF OPERATION.

The applicant participates in Medicare and contracts with all area TennCare MCO's and Virginia Medicaid. Its projected payor mix for this proposed new nuclear medicine service is 60% Medicare and 6% TennCare/Medicaid. Indigent care is projected at 3% of gross revenues under the new ownership.

Table Twelve: Medicare and TennCare/Medicaid Revenues, Year One		
	Medicare	TennCare/Medicaid
Gross Revenue	\$1,238,299	\$123,830
Percent of Gross Revenue	60%	6%

C(II).10. PROVIDE COPIES OF THE BALANCE SHEET AND INCOME STATEMENT FROM THE MOST RECENT REPORTING PERIOD OF THE INSTITUTION, AND THE MOST RECENT AUDITED FINANCIAL STATEMENTS WITH ACCOMPANYING NOTES, IF APPLICABLE. FOR NEW PROJECTS, PROVIDE FINANCIAL INFORMATION FOR THE CORPORATION, PARTNERSHIP, OR PRINCIPAL PARTIES INVOLVED WITH THE PROJECT. COPIES MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND LABELED AS ATTACHMENT C, ECONOMIC FEASIBILITY--10.

These are provided as Attachment C, Economic Feasibility--10.

C(II)11. DESCRIBE ALL ALTERNATIVES TO THIS PROJECT WHICH WERE CONSIDERED AND DISCUSS THE ADVANTAGES AND DISADVANTAGES OF EACH ALTERNATIVE, INCLUDING BUT NOT LIMITED TO:

A. A DISCUSSION REGARDING THE AVAILABILITY OF LESS COSTLY, MORE EFFECTIVE, AND/OR MORE EFFICIENT ALTERNATIVE METHODS OF PROVIDING THE BENEFITS INTENDED BY THE PROPOSAL. IF DEVELOPMENT OF SUCH ALTERNATIVES IS NOT PRACTICABLE, THE APPLICANT SHOULD JUSTIFY WHY NOT, INCLUDING REASONS AS TO WHY THEY WERE REJECTED.

B. THE APPLICANT SHOULD DOCUMENT THAT CONSIDERATION HAS BEEN GIVEN TO ALTERNATIVES TO NEW CONSTRUCTION, E.G., MODERNIZATION OR SHARING ARRANGEMENTS. IT SHOULD BE DOCUMENTED THAT SUPERIOR ALTERNATIVES HAVE BEEN IMPLEMENTED TO THE MAXIMUM EXTENT PRACTICABLE.

A. The applicant knows of no less costly, more effective, or more efficient way to ensure the continuation of this service for patients of its service area. The ODC that was approved to relocate to this same building has announced its intention to close before doing so. Its cardiac PET equipment is vital to the quality of care for patients of this practice. Karing Hearts Cardiology is willing to take over the equipment lease and to offer the service in its practice office. The capital cost to move it into a new location under new ownership is minimal. Relocation of the service, into the heart of the largest medical services provider community in Washington County, provides better access for patients whose physicians would like them to receive cardiac PET scans. By making the service more accessible, the project will increase the use of cardiac PET scanning relative to SPECT studies, with all the attendant cost savings and diagnostic improvements that have been discussed earlier.

B. The project relies entirely on renovation and requires no new construction.

C(III).1. LIST ALL EXISTING HEALTH CARE PROVIDERS (I.E., HOSPITALS, NURSING HOMES, HOME CARE ORGANIZATIONS, ETC.) MANAGED CARE ORGANIZATIONS, ALLIANCES, AND/OR NETWORKS WITH WHICH THE APPLICANT CURRENTLY HAS OR PLANS TO HAVE CONTRACTUAL AND/OR WORKING RELATIONSHIPS, E.G., TRANSFER AGREEMENTS, CONTRACTUAL AGREEMENTS FOR HEALTH SERVICES.

If approved for the relocation, Karing Hearts Cardiology will seek a transfer agreement with MSHA's Johnson City Medical Center, which is less than one mile away on the same street as the practice.

C(III).2. DESCRIBE THE POSITIVE AND/OR NEGATIVE EFFECTS OF THE PROPOSAL ON THE HEALTH CARE SYSTEM. PLEASE BE SURE TO DISCUSS ANY INSTANCES OF DUPLICATION OR COMPETITION ARISING FROM YOUR PROPOSAL, INCLUDING A DESCRIPTION OF THE EFFECT THE PROPOSAL WILL HAVE ON THE UTILIZATION RATES OF EXISTING PROVIDERS IN THE SERVICE AREA OF THE PROJECT.

Because the applicant is proposing to acquire and operate its primary service area's only remaining cardiac PET scanner, and because this is a simple relocation within the same county and service area, it does not seem possible that the project would create any competitive issues, or would duplicate existing technology. The only other such unit in the region will be the cardiac PET at Wellmont Cardiology Services in the adjoining county. That provider has already declared, and documented to the HAS in its approved CN1304-013, that its unit will be fully utilized by its own internal patients who will be switched from using SPECT testing to using cardiac PET testing. So the unit being proposed in this project will not be competing with any other cardiac PET in the region. And, because no conventional PET unit in the service area seems to have both the capability and the capacity to provide additional cardiac PET scans, it seems unlikely that the relocation and change of ownership of the Gray cardiac PET system could create any competitive issues with any conventional PET in the area.

C(III).3. PROVIDE THE CURRENT AND/OR ANTICIPATED STAFFING PATTERN FOR ALL EMPLOYEES PROVIDING PATIENT CARE FOR THE PROJECT. THIS CAN BE REPORTED USING FTE'S FOR THESE POSITIONS. IN ADDITION, PLEASE COMPARE THE CLINICAL STAFF SALARIES IN THE PROPOSAL TO PREVAILING WAGE PATTERNS IN THE SERVICE AREA AS PUBLISHED BY THE TENNESSEE DEPARTMENT OF LABOR & WORKFORCE DEVELOPMENT AND/OR OTHER DOCUMENTED SOURCES.

Please see the following page for Table Fourteen, projected FTE's and salary ranges.

The Department of Labor and Workforce Development website indicates the following annual salary information in the area, for clinical employees of the type to be employed in this project:

Table Thirteen: TDOL Surveyed Average Salaries for the Service Area				
Position	Entry Level	Mean	Median	Experienced
RN	\$40,450	\$57,870	\$56,050	\$66,590
Nuclear Med. Tech*	\$54,290	\$60,050	\$59,210	\$62,940

**This position was not surveyed in the Johnson City region. Data here is for Kingsport area, the closest comparable market.*

Table Fourteen: Karing Hearts Cardiology, PLLC--Cardiac PET Service Staffing Requirements				
Position Type (RN, etc.)	Current FTE's	Year One FTE's	Year Two FTE's	Salary Range (Annual)
Registered Nurse	0	0.5	0.5	\$40k - \$50k/yr
Nuclear Medicine Technologist	0	1	1	\$65k - \$75k/yr
Reception	0	0.5	0.5	\$25k - \$30k/yr
Total FTE's				

C(III).4. DISCUSS THE AVAILABILITY OF AND ACCESSIBILITY TO HUMAN RESOURCES REQUIRED BY THE PROPOSAL, INCLUDING ADEQUATE PROFESSIONAL STAFF, AS PER THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, AND/OR THE DIVISION OF MENTAL RETARDATION SERVICES LICENSING REQUIREMENTS.

The project will obtain its nuclear medicine tech from the ODC that is closing this service. The RN will be shared with the practice.

C(III).5. VERIFY THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSING CERTIFICATION AS REQUIRED BY THE STATE OF TENNESSEE FOR MEDICAL/CLINICAL STAFF. THESE INCLUDE, WITHOUT LIMITATION, REGULATIONS CONCERNING PHYSICIAN SUPERVISION, CREDENTIALING, ADMISSIONS PRIVILEGES, QUALITY ASSURANCE POLICIES AND PROGRAMS, UTILIZATION REVIEW PPOLICIES AND PROGRAMS, RECORD KEEPING, AND STAFF EDUCATION.

The applicant is familiar with the licensing requirements for a nuclear medicine tech, a Registered Nurse, and the licensing requirements for handling radioactive isotopes and materials.

C(III).6. DISCUSS YOUR HEALTH CARE INSTITUTION'S PARTICIPATION IN THE TRAINING OF STUDENTS IN THE AREAS OF MEDICINE, NURSING, SOCIAL WORK, ETC. (I.E., INTERNSHIPS, RESIDENCIES, ETC.).

This small practice is not currently affiliated with any health professional training programs at the present time. However, the applicant would be pleased to consider offering a clinical rotation for cardiac PET studies, if it acquires this new service and if a local training program would be interested in such an addition.

C(III).7(a). PLEASE VERIFY, AS APPLICABLE, THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSURE REQUIREMENTS OF THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, THE DIVISION OF MENTAL RETARDATION SERVICES, AND/OR ANY APPLICABLE MEDICARE REQUIREMENTS.

The applicant so verifies. No facility license is required from TDH. The Department of Environment and Conservation, however, already licenses this practice to handle radioactive materials for nuclear medicine studies.

C(III).7(b). PROVIDE THE NAME OF THE ENTITY FROM WHICH THE APPLICANT HAS RECEIVED OR WILL RECEIVE LICENSURE, CERTIFICATION, AND/OR ACCREDITATION

LICENSURE: Radioactive Materials License
from Tennessee Department of Environment
and Conservation

CERTIFICATION: Medicare Certification from CMS
TennCare Certification from TDH

ACCREDITATION: Intersocietal Commission on Accreditation

C(III).7(c). IF AN EXISTING INSTITUTION, PLEASE DESCRIBE THE CURRENT STANDING WITH ANY LICENSING, CERTIFYING, OR ACCREDITING AGENCY OR AGENCY.

The applicant physician practice is currently certified for participation in Medicare and Medicaid/TennCare, and licensed to handle radioactive materials. It will seek accreditation for its PET service from Intersocietal Commission on Accreditation.

C(III).7(d). FOR EXISTING LICENSED PROVIDERS, DOCUMENT THAT ALL DEFICIENCIES (IF ANY) CITED IN THE LAST LICENSURE CERTIFICATION AND INSPECTION HAVE BEEN ADDRESSED THROUGH AN APPROVED PLAN OF CORRECTION. PLEASE INCLUDE A COPY OF THE MOST RECENT LICENSURE/CERTIFICATION INSPECTION WITH AN APPROVED PLAN OF CORRECTION.

Not applicable to a private medical practice.

C(III)8. DOCUMENT AND EXPLAIN ANY FINAL ORDERS OR JUDGMENTS ENTERED IN ANY STATE OR COUNTRY BY A LICENSING AGENCY OR COURT AGAINST PROFESSIONAL LICENSES HELD BY THE APPLICANT OR ANY ENTITIES OR PERSONS WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE APPLICANT. SUCH INFORMATION IS TO BE PROVIDED FOR LICENSES REGARDLESS OF WHETHER SUCH LICENSE IS CURRENTLY HELD.

None.

C(III)9. IDENTIFY AND EXPLAIN ANY FINAL CIVIL OR CRIMINAL JUDGMENTS FOR FRAUD OR THEFT AGAINST ANY PERSON OR ENTITY WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE PROJECT.

None.

C(III)10. IF THE PROPOSAL IS APPROVED, PLEASE DISCUSS WHETHER THE APPLICANT WILL PROVIDE THE THSDA AND/OR THE REVIEWING AGENCY INFORMATION CONCERNING THE NUMBER OF PATIENTS TREATED, THE NUMBER AND TYPE OF PROCEDURES PERFORMED, AND OTHER DATA AS REQUIRED.

Yes. The applicant will provide the requested data consistent with Federal HIPAA requirements.

PROOF OF PUBLICATION

Attached.

DEVELOPMENT SCHEDULE

1. PLEASE COMPLETE THE PROJECT COMPLETION FORECAST CHART ON THE NEXT PAGE. IF THE PROJECT WILL BE COMPLETED IN MULTIPLE PHASES, PLEASE IDENTIFY THE ANTICIPATED COMPLETION DATE FOR EACH PHASE.

The Project Completion Forecast Chart is provided after this page.

2. IF THE RESPONSE TO THE PRECEDING QUESTION INDICATES THAT THE APPLICANT DOES NOT ANTICIPATE COMPLETING THE PROJECT WITHIN THE PERIOD OF VALIDITY AS DEFINED IN THE PRECEDING PARAGRAPH, PLEASE STATE BELOW ANY REQUEST FOR AN EXTENDED SCHEDULE AND DOCUMENT THE "GOOD CAUSE" FOR SUCH AN EXTENSION.

Not applicable. The applicant anticipates completing the project within the period of validity.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision Date, as published in Rule 68-11-1609(c):

February 26, 2014

Assuming the CON decision becomes the final Agency action on that date, indicate the number of days from the above agency decision date to each phase of the completion forecast.

PHASE	DAYS REQUIRED	Anticipated Date (MONTH /YEAR)
1. Architectural & engineering contract signed	2	3-1-14
2. Construction documents approved by TDH	na	na
3. Construction contract signed	17	3-15-14
4. Building permit secured	20	3-18-14
5. Site preparation completed	na	na
6. Building construction commenced	32	4-1-14
7. Construction 40% complete	92	6-1-14
8. Construction 80% complete	152	8-1-14
9. Construction 100% complete	212	10-1-14
10. * Issuance of license (if required)	na	na
11. *Initiation of service	227	10-15-14
12. Final architectural certification of payment	287	12-15-14
13. Final Project Report Form (HF0055)	317	1-14-15

*** For projects that do NOT involve construction or renovation: please complete items 10-11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

INDEX OF ATTACHMENTS

A.4	Ownership--Legal Entity and Organization Chart (if applicable)
A.6	Site Control and Documentation of Building Market Value
B.II.E.3	Major Medical Equipment-- Draft Lease; Market Value
B.III.	Plot Plan
B.IV.	Floor Plan
C, Need--1A	Documentation of Project-Specific Criteria <ul style="list-style-type: none"> 1. Qualifications of Dr. Jeffrey Schoondyke 2. Qualifications of Dr. Melanie Davidson 3. Emergency Response Protocols 4. Medical Necessity Protocols 5. Medical Director Specifications
C, Need--1.A.3.	Letters of Intent <ul style="list-style-type: none"> 1. ODC's Letter of Intent to Surrender CN1304-014 and to Cease Operation 2. Letter of Intent from Radiopharmaceutical Vendor
C, Need--3	Service Area Maps
C, Economic Feasibility--1	Documentation of Construction Cost Estimate
C, Economic Feasibility--2	Documentation of Availability of Funding
C, Economic Feasibility--10	Financial Statements of Applicant
Miscellaneous Information	<ul style="list-style-type: none"> 1. TennCare Statistics 2. PSA Demographic Data Source 3. Articles on Cardiac PET Technology 4. Medically Underserved Areas in the Project Service Area
Support Letters	

A.4--Ownership
Legal Entity and Organization Chart

State of Tennessee



Department of State
Corporate Filings
312 Eighth Avenue North
6th Floor, William R. Snodgrass Tower
Nashville, TN 37243

ARTICLES OF AMENDMENT
TO ARTICLES OF ORGANIZATION
(LLC)

RECEIVED
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2011 MAR 11 AM 8:33

TRE HARBETT
SECRETARY OF STATE

6045.3054

LIMITED LIABILITY COMPANY CONTROL NUMBER (IF KNOWN) 000651483

PURSUANT TO THE PROVISIONS OF §48-209-104 OF THE TENNESSEE LIMITED LIABILITY COMPANY ACT OR §48-249-204 OF THE TENNESSEE REVISED LIMITED LIABILITY COMPANY ACT, THE UNDERSIGNED ADOPTS THE FOLLOWING ARTICLES OF AMENDMENT TO ITS ARTICLES OF ORGANIZATION:

PLEASE MARK THE BLOCK THAT APPLIES:

- ☒ AMENDMENT IS TO BE EFFECTIVE WHEN FILED BY THE SECRETARY OF STATE.
☐ AMENDMENT IS TO BE EFFECTIVE _____, _____ (DATE) _____ (TIME).
(NOT TO BE LATER THAN THE 90TH DAY AFTER THE DATE THIS DOCUMENT IS FILED.) IF
NEITHER BLOCK IS CHECKED, THE AMENDMENT WILL BE EFFECTIVE AT THE TIME OF
FILING.

1. PLEASE INSERT THE NAME OF THE LIMITED LIABILITY COMPANY AS IT APPEARS ON
RECORD: Heart and Vascular of East Tennessee, PLLC

IF CHANGING THE NAME, INSERT THE NEW NAME ON THE LINE BELOW:

Karing Hearts Cardiology, PLLC

2. PLEASE INSERT ANY CHANGES THAT APPLY:

A. PRINCIPAL ADDRESS: _____
STREET ADDRESS

CITY STATE/COUNTY ZIP CODE

B. REGISTERED AGENT: _____

C. REGISTERED ADDRESS: _____

STREET
TN

CITY STATE ZIP CODE COUNTY

D. OTHER CHANGES:

3. THE AMENDMENT WAS DULY ADOPTED ON March 9 2011
MONTH DAY YEAR

(If the amendment is filed pursuant to the provision of §48-209-104 of the TN LLC Act, please also
complete the following by checking one of the two boxes:) AND THE AMENDMENT WAS DULY
ADOPTED BY THE

☐ BOARD OF GOVERNORS WITHOUT MEMBER APPROVAL AS SUCH WAS NOT REQUIRED
☒ MEMBERS

Sole Member

SIGNER'S CAPACITY

SIGNATURE

Jeffrey Schoondyke

NAME OF SIGNER (TYPED OR PRINTED)



STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

Heart and Vascular of East Tennessee, PLLC
110 Corporate Drive, Suite 150
Johnson City, TN 37604

February 22, 2011

Filing Acknowledgment

Please review the filing information below and notify our office immediately of any discrepancies.

Control # :	651483	Formation Locale:	Washington County
Filing Type:	Limited Liability Company - Domestic	Date Formed:	02/18/2011
Filing Date:	02/18/2011 10:04 AM	Fiscal Year Close	12
Status:	Active	Annual Rpt Due:	04/01/2012
Duration Term:	Perpetual	Image # :	6834-2999
Managed By:	Manager Managed		

Document Receipt

Receipt # : 351058	Filing Fee:	\$300.00
Payment-Check/MO - KLEIN & ASSOCIATES ATTORNEYS AT LAW, Johnson City, TN		\$300.00

Registered Agent Address

RODNEY S KLEIN
110 CORPORATE DR
STE 150
Johnson City, TN 37604

Congratulations on the successful filing of your **Articles of Organization** for **Heart and Vascular of East Tennessee, PLLC** in the State of Tennessee which is effective on the date shown above. You must also file this document in the office of the Register of Deeds in the county where the entity has its principal office if such principal office is in Tennessee.

You must file an Annual Report with this office on or before the Annual Report Due Date noted above and maintain a Registered Office and Registered Agent. Failure to do so will subject the business to Administrative Dissolution/Revocation.


Tre Hargett
Secretary of State

Processed By: Jeff Cook

FILED

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STATE OF TENNESSEE

2011 FEB 18 AM 10:04

**Tennessee Articles of Organization of
a Professional Limited Liability Company**

TRE HARGETT
SECRETARY OF STATE

This company is organized under the Tennessee Revised Limited Liability Company Act, more specifically, Tenn. Code Ann. §48-249-1101 et seq.

1. The name of the Professional Limited Liability Company is: Heart and Vascular of East Tennessee, PLLC.
2. The name and address of the Professional Limited Liability Company's initial registered office in Tennessee is: Rodney S. Klein, Esq., Klein & Associates, 110 Corporate Drive, Suite 150, Johnson City, TN 37604 in Washington County, Tennessee.
3. Number of members at the time of organization is 1.
4. The Professional Limited Liability Company will be manager managed.
5. This document is to be effective as of the date of filing.
6. The complete address of the Professional Limited Liability Company's principal office is: 110 Corporate Drive, Suite 150, Johnson City, TN 37604 in Washington County, Tennessee.
7. The Period of Duration is perpetual.
8. The purpose of the Professional Limited Liability Company is to render medical services and other ancillary services.
9. The Professional Limited Liability Company has one or more qualified members and no disqualified members.

2-16-2011
Signature Date

Managing Member
Signer's Capacity

Jeffrey Schoondyke
Signature (manager or member authorized to
sign by the Professional Limited Liability Company)

Jeffrey Schoondyke, MD
Name

ROLL/IMG: 713/1158-1159
11003342

2 PGS : AL - ARTICLES OF ORGANIZATION	
CHELSEA BATCH: 46539 03/02/2011 - 09:20 AM	
VALUE	0.00
MORTGAGE TAX	0.00
TRANSFER TAX	0.00
RECORDING FEE	5.00
ARCHIVE FEE	0.00
DP FEE	2.00
REGISTER'S FEE	0.00
TOTAL AMOUNT	7.00

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Business Entity Detail

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- [Certificate of Existence](#)
- [Change Registered Agent](#)

000651483: Limited Liability Company - Domestic

[Printer Friendly Version](#)

Name: Karing Hearts Cardiology, PLLC
Old Name: Heart and Vascular of East Tennessee, PLLC

Status: Active
Formed in: TENNESSEE
Fiscal Year Close: December
Term of Duration: Perpetual

Principal Office: 701 N STATE OF FRANKLIN RD
 STE 2
 JOHNSON CITY, TN 37604-3645 USA

Mailing Address: 701 N STATE OF FRANKLIN RD
 STE 2
 JOHNSON CITY, TN 37604-3645 USA

AR Exempt: No
Managed By: Manager Managed

Initial Filing Date: 02/18/2011
Delayed Effective Date:
AR Due Date: 04/01/2014
Inactive Date:

Obligated Member Entity: No
Number of Members: 1

[Assumed Names](#)
[History](#)
[Registered Agent](#)

Name

Status

Expires

No Assumed Names Found...

Division of Business Services
 312 Rosa L. Parks Avenue, Snodgrass Tower, 6th Floor
 Nashville, TN 37243
 615-741-2286

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STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH
WILLIAM R. SNODGRASS TENNESSEE TOWER
312 ROSA L. PARKS AVENUE, 15TH FLOOR
NASHVILLE, TENNESSEE 37243

August 30, 2013

Karing Hearts Cardiology
701 N. State of Franklin Road, Suite 2
Johnson City, Tennessee 37604-3645

Attention: Monica Charmaine Hart, CNMT, Radiation Safety Officer

Attached to this letter is your Tennessee Radioactive Material License R-90054-H23 issued to expire on August 31, 2023.

"State Regulations for Protection Against Radiation", referred to in Condition 12 of the license conditions, may be accessed from the internet website: www.tn.gov/sos/rules/0400/0400-20/0400-20.htm. Enclosed are several copies of Form RHS 8-3 for posting as noted on that form. Your attention is directed to State Regulations and to specific license Conditions 11 through 20 which are to be followed in the use of this license.

Please contact us if we can be of further assistance to you.

Sincerely,

A handwritten signature in dark ink, appearing to read "R. Parsons", is written over a horizontal line.

Ronald J. Parsons
Division of Radiological Health



**TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH
WILLIAM R. SNODGRASS TENNESSEE TOWER, 15TH FLOOR
312 ROSA L. PARKS AVENUE, NASHVILLE, TENNESSEE 37243**

RADIOACTIVE MATERIAL LICENSE

Pursuant to Tennessee Department of Environment and Conservation Regulations, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the Tennessee Department of Environment and Conservation and orders of the Division of Radiological Health, now or hereafter in effect and to any conditions specified below.

LICENSEE 1. Name Karing Hearts Cardiology 2. Address 701 N. State of Franklin Road, Suite 2 Johnson City, Tennessee 37604-3645		3. License number R-90054-H23 amended in its entirety
		4. Expiration date August 31, 2023
		5. File no. R-90054
6. Radioactive Material (Element and Mass Number)	8. Chemical and/or physical form	9. Maximum Radioactivity and/or quantity of material which licensee may possess at any one time.
See Supplementary Sheets		
10. Authorized Use See Supplementary Sheets		

CONDITIONS


11. Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above.

See Supplementary Sheets

Date of Issuance August 30, 2013

Page 1 of 4 Pages

For the Commissioner
Tennessee Department of Environment and Conservation

By: 
 Division of Radiological Health
 Ronald J. Parsons
 Health Physicist



**TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH
WILLIAM R. SNODGRASS TENNESSEE TOWER, 15TH FLOOR
312 ROSA L. PARKS AVENUE, NASHVILLE, TENNESSEE 37243**

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

Page 2 of 4 Pages

License Number R-90054-H23

- | | | |
|---|---|---|
| <p>6. <u>Radioactive Material</u>
(Element and
Mass Number)</p> | <p>8. <u>Chemical</u>
and/or
<u>Physical Form</u></p> | <p>9. <u>Maximum Radioactivity</u>
and/or <u>Quantity of Material</u>
Which Licensee May
<u>Possess at Any One Time</u></p> |
| <p>A. Any radioactive material
as permitted in Rule
0400-20-07-.38 of
"State Regulations for
Protection Against
Radiation."</p> | <p>A. Any</p> | <p>A. As necessary for the
uses authorized in
Item 10.A.</p> |
| <p>B. Any radioactive material
as permitted in Rule
0400-20-07-.40 of
"State Regulations for
Protection Against
Radiation."</p> | <p>B. Any, except generators</p> | <p>B. As necessary for the
uses authorized in
Item 10.B.</p> |
| <p>C. Any radioactive material</p> | <p>C. As specified in
"State Regulations for
Protection Against
Radiation" 0400-20-
07-.31.</p> | <p>C. As specified in
"State Regulations
for Protection Against
Radiation" 0400-20-
07-.31.</p> |

10. Authorized Uses

- A. Uptake, dilution, excretion studies for which a written directive is not required.
(Rule 0400-20-07-.38 of "State Regulations for Protection Against Radiation.")
- B. Imaging and localization studies for which a written directive is not required.
(Rule 0400-20-07-.40 of "State Regulations for Protection Against Radiation.")
- C. Calibration, reference, or transmission sources.
(Rule 0400-20-07-.31 of "State Regulations for Protection Against Radiation.")

Conditions (continued)

- 12. The licensee shall comply with applicable provisions of 0400-20-04, 0400-20-05, 0400-20-07, and 0400-20-10 of "State Regulations for Protection Against Radiation."
- 13. The Radiation Safety Officer for this license is Monica Charmaine Hart, CNMT.



**TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH
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RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

Page 3 of 4 Pages

License Number R-90054-H23

14. Licensed material is only authorized for-use by, or under the supervision of:
- A. Individuals permitted to work as authorized users in accordance with "State Regulations or Protection Against Radiation" 0400-02-07-.13 and 0400-20-07-.14.
 - B. The following authorized users for the material and medical uses as specified:

All material authorized by this license:

Christopher J. Downs, M.D. Steven M. Smith, M.D.
Jeffrey W. Schoondyke, M.D.
15. A. Sealed sources authorized by this license shall be tested for leakage and/or contamination in accordance with "State Regulations for Protection Against Radiation" 0400-20-07-.32.
- B. Records of leak tests shall be retained in accordance with "State Regulations for Protection Against Radiation" 0400-20-07-.111.
- C. Tests for leakage and/or contamination shall be performed by persons authorized by this Department, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform such services.
16. The licensee shall not open sealed sources containing radioactive material.
17. The licensee is authorized to hold radioactive material with a physical half-life of 120 days or less for decay-in-storage before disposal in ordinary trash provided:
- A. Before disposal as ordinary trash, radioactive waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - B. A record of each disposal made under this condition shall be retained for three years. The record must include the date of disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
18. The licensee may use a shield device for performing linearity tests of his dose calibrator provided he or she follows the manufacturer's procedures for its use. These procedures shall be maintained for inspection by the Department.



**TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH
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RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

Page 4 of 4 Pages

License Number R-90054-H23

19. No provision of this license relieves the licensee from compliance with other Federal, State and local laws, ordinances, and regulations applicable to the licensee's activities.
20. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 8, and 9 of this license in accordance with statements, representations, and procedures contained in the following:
 - Application dated July 25, 2013, with attachments.

A.6--Site Control

Residential and/or Commercial Lease

APPLICANTS
SITE
CONTROL

This lease is made on the 1 day of September, 2013.

The Landlord hereby agrees to lease to the Tenant, and the Tenant agrees to lease from the Landlord, the Leased Premises described below pursuant to the terms and conditions specified herein:

LANDLORD:

Jeffrey W. Schoondyke
212 Highland Gate Dr.
Johnson City, TN
37615

TENANT:

Karing Hearts Cardiology, PLLC
201 N State of Franklin, Ste 2
Johnson City, TN 37604

1. LEASED PREMISES: The Leased Premises described as: 201 N State of Franklin Ste 2, 3
8083 sq ft
2. TERM: Term of the Lease shall be for a term of 5 years, beginning on the 1 day of October and ending on Midnight of the 30 day of September 2018.
Tenant must give Landlord a written thirty (30) day notice prior to vacating premises, beginning from the first of the month to the last day of the following month. Tenancy is month to month after lease term.
3. RENT: The monthly rental amount for the Leased Premises is \$9,083 per month. \$12.00/sq ft
The rent payment must be paid by the first day of each month at the Landlord's address listed above. The first month's rent is to be paid when Tenant signs this lease. Landlord need not give notice to Tenant regarding Tenant's obligation to pay rent. A grace period until the fifth day of the month will be allowed, however, after the fifth of the month a 10% late charge will be added.
4. SECURITY DEPOSIT: Upon Tenant's execution of this Lease, Tenant shall make a security deposit of \$1st mo Rent to Landlord in order to ensure that Tenant complies with the terms and conditions of the Lease. If Tenant fully complies, Landlord will return the security deposit within two weeks after the date Tenant delivers possession of the Leased Premises to Landlord. If Tenant does not fully comply with the terms of the Lease, Landlord may use the security deposit to pay amounts owed by Tenant, including damages. Security deposit is not to be used in lieu of last month's rent.
5. DEFAULT/ABANDONMENT: If Tenant defaults in the payment of rent or any term or condition of this lease, Landlord may give tenant written notice to cure such default. If Tenant fails to cure such default with ten days of receiving notice, Landlord may elect to

terminate the lease, re-enter the Lease Premises and remove the Tenant, all other occupants and their possessions and any costs incurred by Landlord in enforcing these rights shall be deemed additional rent.

If Tenant abandons or vacates the Leased Premises during the term of the lease, Landlord may elect to re-enter the premises, without liability for prosecution or owing damages to Tenant, and, at Landlord's option, release the Leased Premises. If Landlord elects not to release the Leased Premises, Tenant shall be liable for the remainder of the rent due under the Lease until its expiration. If Landlord releases the Leased Premises but is unable to re-lease the Leased Premises for as much rent as would have been paid by Tenant during the period between Tenant's abandonment and the end of the Term, Tenant shall be liable to Landlord for the difference. Landlord may also dispose of any property left by Tenant after abandonment with liability and apply the proceeds to reduce such difference. Tenant shall make all rental payment in full. Payment or receipt of a rental payment of less than the amount stated in the lease shall be deemed partial payment.

Should legal proceedings be necessary, Washington County, TN Courts shall have jurisdiction to litigate all issues between the parties relating to this lease. All parties signing shall submit to the jurisdiction of the Courts of Washington County, TN.

6. OCCUPANTS: The Leased Premises shall be occupied by the following persons only:

No other persons shall occupy the Leased Premises without the advance written consent of the Landlord. The authorized occupants may only use the Leased Premises for commercial purposes and may not utilize the premises for residential purposes.

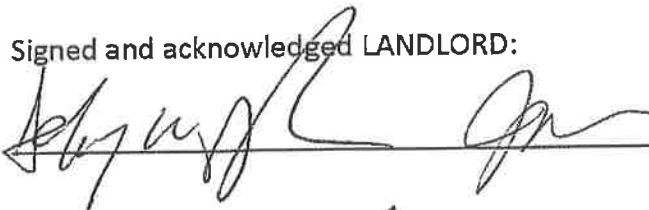
7. REPAIRS: Tenant must take good care of the Leased Premises and all equipment and fixtures contained therein. Tenant is responsible and liable for all repairs, replacements and damages caused by or required as a result of any acts or neglect of Tenant, Occupants, invitees or guests. If Tenant fails to make a needed repair or replacement, Landlord may do it and add the expenses to the rent.
8. PARTIAL OR TOTAL DESTRUCTION OF LEASED PREMISES: If the Leased Premises are partially damaged or completely destroyed by a fire or other occurrence that is not caused by the Tenant's negligence or willful acts (or the negligence of Tenant's family, agents or guests) Landlord may elect to: (1) repair or rebuild the Leased Premises during the period of untenability and abate the rent proportionally for the this period; or (2)

not repair or rebuild the Leased Premises, terminate the lease and prorate the rent up to the time of the damage.

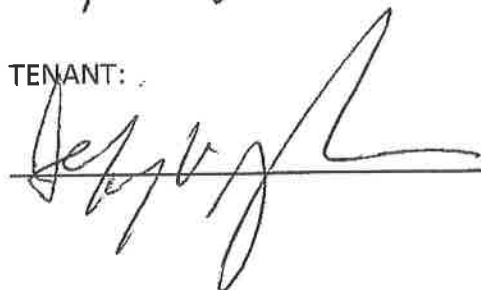
9. ALTERATION: Tenant must obtain Landlord's prior written consent to paint or wallpaper the Leased Premises or to install any paneling, flooring, partitions, railings, or make any other alterations. Tenant must not alter the plumbing, ventilation, air-conditioning, heating or electrical systems. All the alterations, installations and improvements shall become property of the Landlord when completed and paid for, and shall be surrendered as part of the Leased Premises at the end of the term. Landlord is not required to pay for any of the work performed under this section unless; Landlord has agreed to pay as indicated in the prior written consent required by this paragraph.
10. MAINTENANCE OF LEASED PREMISES: Tenant shall, at Tenant's expense, maintain the premises in a clean and sanitary condition at all times. At the end of the term, Tenant will leave the Leased Premises clean and in good condition, with the exception of ordinary wear and tear. Tenant shall remove all Tenant's belongings and surrender all keys to the Landlord upon the expiration of the lease. Tenant shall change A/C filters monthly.
11. ASSIGNMENT/SUBLETTING RESTRICTIONS: Tenant may not assign this agreement or sublet the Leased Premises without the prior written consent of the Landlord. Any assignment, sublease or other purported license to use the Leased Premises by Tenant without the Landlord's consent shall be void and shall (at the Landlord's option) terminate this lease.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease Agreement as of the date first set forth above.

Signed and acknowledged LANDLORD:

 Date 11/12/13

TENANT:

 Date 11/12/13

BRANDT AND BEESON, P.C.
Attorneys at Law
206 Princeton Road, Suite 25
Johnson City, Tennessee 37601

LESSORS
DEED TO
"701" BUILDING

FREDERIC H. BRANDT
D. R. BEESON, III

July 30, 2013

Telephone (423) 282-1981
Facsimile (423) 610-6984
Or (423) 283-4778

Mr. and Mrs. Jeffrey W. Schoondyke
701 N. State of Franklin Rd, Ste. 2
Johnson City, TN 37604

Re: 701 N. State of Franklin Road

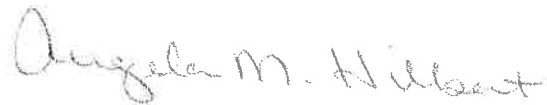
Dear Mr. and Mrs. Schoondyke:

Enclosed please find the original recorded Warranty Deed with regard to the above-captioned matter, which has now been recorded in the Register's Office for Washington County, Tennessee.

Should you have any questions, please feel free to call on me.

Very truly yours,

BRANDT and BEESON, P.C.



Angela M. Hilbert
Legal Assistant

AMH

Enclosure

This Instrument Prepared By:
Brandt and Beeson, P.C.
Attorneys at Law
206 Princeton Road, Suite 25
Johnson City, TN 37601
(423)282-1981

ROLL/IMG: 807/1674-1676

13013040

3 PGS : AL - DEED	
JACKIE BATCH: 91094	07/24/2013 - 12:50 PM
VALUE	2771044.00
MORTGAGE TAX	0.00
TRANSFER TAX	10252.86
RECORDING FEE	15.00
ARCHIVE FEE	0.00
DP FEE	2.00
REGISTER'S FEE	1.00
TOTAL AMOUNT	10270.86
STATE OF TENNESSEE, WASHINGTON COUNTY	
GINGER B. JILTON	
REGISTER OF DEEDS	

Warranty Deed

THIS INDENTURE made and entered into on this the 23rd day of July, 2013, by and between **701 FRANKLIN, L.L.C., a Tennessee limited liability company**, Party of the First Part, and **JEFFREY W. SCHOONDYKE and wife, JENNIFER M. SCHOONDYKE**, Parties of the Second Part.

WITNESSETH:

That for and in consideration of the sum of \$10.00 cash in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, the Party of the First Part has bargained and sold, and by these presents does hereby transfer and convey unto the Parties of the Second Part, their heirs and assigns, the following described real property, to-wit:

Situate, lying and being in the 9th Civil District of Washington County, Tennessee, and more particularly described as follows:

BEGINNING at an iron rod on the southerly right of way line of State of Franklin Road and the easterly right of way line of Clinchfield Street; thence with said right of way line of State of Franklin Road, S. 46° 17' E., 438.92 feet to an iron rod on the westerly right of way line of Lark Street; thence with said Lark Street right of way line the following four courses: 1) S. 01° 24' 12" W., 56.84 feet to an iron rod; 2) a nontangent curve to the right (Chord S. 12° 52' 29" W., 77.79 feet, Radius 175.78 feet, Delta 25° 34' 02", Length 78.44 feet), 3) S. 17° 14' 13" E., 36.67 feet to an iron rod; 4) S. 02° 41' 00" W., 1.87 feet to an iron rod, being the common corner between Lots 1 and 2 of State of Franklin Road Properties Subdivision, Section 1; thence with said Lot 2, N. 88° 18' 09" W., 210.03 feet to an iron rod, being common corner to J. M. Cox, Jr. property (Roll 33, Image 251); thence with said Cox property the following three courses: 1) N. 02° 41' 00" E., 84.34 feet to an iron rod; 2) N. 46° 17' 00" W., 199.90 feet to an iron rod; 3) N. 86° 40' 30" W., 50.00 feet to an iron rod on the easterly right of way line of Clinchfield Street; thence with said right of way the following five courses: 1) N. 03° 19' 30" E., 120.30 feet to an iron rod; 2) S. 88° 58' 00" E., 8.58 feet

to an iron rod; 3) N. 02° 06' 29" E., 47.78 feet to an iron rod; 4) N. 22° 52' 42" E., 80.79 feet to an iron rod, and 5) S. 88° 58' 08" E., 42.38 feet to the point of BEGINNING, containing 2.41 acres and being all of Lot 1, State of Franklin Road Properties Subdivision, Section I, as shown on Replat of said Subdivision of record in Plat Book 12, page 43, in the Register's Office for Washington County, Tennessee.

AND BEING the same property conveyed to 701 Franklin, LLC, a Tennessee limited liability company, by deed from J. M. Cox, Jr., dated December 23, 1997, of record on Roll 128, Image 1766, in the Register's Office for Washington County, Tennessee.

Tax Assessor's Property ID No.: Map 45-M, Group E, Parcel 1.00.

TO HAVE AND TO HOLD the above-described property, together with all the rights, privileges and appurtenances thereunto appertaining unto the Parties of the Second Part, their heirs and assigns, forever in fee simple.

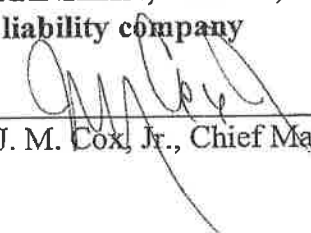
The Party of the First Part warrants that it is lawfully seized and possessed of the above-described property; that it has a good and perfect right to convey the same; that said property is free and unencumbered; and the title thereto, as herein made, it will forever warrant and defend against the lawful claims and demands of all persons whomsoever.

This conveyance is made subject to valid restrictive covenants and easements, if any, appearing of record.

IN TESTIMONY WHEREOF, the Party of the First Part has executed this instrument the day and year first above written.

**701 FRANKLIN, L.L.C., a Tennessee
limited liability company**

BY: _____


J. M. Cox, Jr., Chief Manager

STATE OF TENNESSEE
COUNTY OF WASHINGTON

Before me, the undersigned Notary Public of the State and County aforesaid, personally appeared J. M. Cox, Jr., with whom I am personally acquainted (or proved to me on the basis of satisfactory evidence), and who, upon oath, acknowledged himself to be Chief Manager of 701 FRANKLIN, L.L.C., the within named bargainer, a Tennessee limited liability company, and that he as such officer, executed the foregoing instrument for the purpose therein contained, by signing the name of the limited liability company by himself as such officer.

WITNESS my hand and seal, this 23rd day of July, 2013.

Angela M. Hilbert
NOTARY PUBLIC

My Commission Expires: 07-26-2014



STATE OF TENNESSEE
COUNTY OF WASHINGTON

I, or we, hereby swear or affirm that the actual consideration for this transfer, or value of the property or interest in property transferred, whichever is greater, is \$2,771,044.00, which amount is equal to or greater than the amount which the property or interest would command at a fair and voluntary sale.

Jeffrey W. Schoondyke
Affiant

Subscribed and sworn before me this the 23rd day of July, 2013.

My Commission Expires: 07-26-2014

Angela M. Hilbert
Notary Public



PROPERTY OWNER

Name & Address:

Jeffrey W. Schoondyke and Jennifer M. Schoondyke
701 W. State of Franklin Rd Ste 2
Johnson City, TN 37604

Person or agency responsible
for payment of taxes

Same

F:\NetDocs\Angie\20490-Schoondyke (TSB)\Warranty Deed.wpd

A. Settlement Statement

U.S. Department of Housing
and Urban Development

SALE PRICE
OF BUILDING

OMB Approval No. 2502-0265



B. Type of Loan

☐ FHA 2. ☐ RHS 3. ☒ Conv. Unins.

6. File Number
20490

7. Loan Number

8. Mortgage Insurance Case Number

4. ☐ VA 5. ☐ Conv. Ins.

C. Note: This form is furnished to give you a statement of actual settlement costs. Amounts paid to and by the settlement agent are shown. Items marked "(p.o.c.)" were paid outside the closing; they are shown here for information purposes and are not included in the totals.

D. Name and Address of Borrower
Jeffrey W. Schoondyke
Jennifer M. Schoondyke

E. Name and Address of Seller
State of Franklin Bank, QI for 701 Franklin, LLC

F. Name and Address of Lender
TriSummit Bank
862 Med Tech Parkway
Johnson City, TN 37604

G. Property Location

701 N. State of Franklin Road
Johnson City, TN 37604

H. Settlement Agent

Brandt and Beeson, P.C.

Place of Settlement
206 Princeton Road, Suite 25
Johnson City TN

I. Settlement Date

07/23/13

DD: 07/23/13

J. SUMMARY OF BORROWER'S TRANSACTION:

100. GROSS AMOUNT DUE FROM BORROWER

101. Contract sales price	2,771,044.00
102. Personal property	
103. Settlement charges to borrower (line 1400)	29,931.46
104.	
105.	

Adjustments for items paid by seller in advance

106. City/town taxes	to	
107. County taxes	to	
108. Assessments	to	
109. CAM due to Seller thru 7/23/13		221.33
110.		
111.		
112.		

120. GROSS AMOUNT DUE FROM BORROWER

2,801,196.79

200. AMOUNTS PAID BY OR IN BEHALF OF BORROWER

201. Deposit or earnest money	5,000.00
202. Principal amount of new loan(s)	2,216,800.00
203. Existing loan(s) taken subject to	
204.	
205. Second Note	554,200.00
TriSummit Bank	
206.	
207.	
208. Seller Contributions for Tenant Improvemen	20,000.00
209.	

Adjustments for items unpaid by seller

210. City/town taxes	01/01 to 07/23	7,490.99
211. County taxes	01/01 to 07/23	9,131.70
212. Assessments	to	
213. July Base Rent Due Buyer 8 Days		5,042.17
214. July CAM due Buyer 8 Days		976.06
215.		
216. Security Deposits Held		13,292.00
217.		
218.		
219.		

220. TOTAL PAID BY / FOR BORROWER

2,831,932.92

K. SUMMARY OF SELLER'S TRANSACTION:

400. GROSS AMOUNT DUE TO SELLER

401. Contract sales price	2,771,044.00
402. Personal property	
403.	
404.	
405.	

Adjustments for items paid by seller in advance

406. City/town taxes	to	
407. County taxes	to	
408. Assessments	to	
409. CAM due to Seller thru 7/23/13		221.33
410.		
411.		
412.		

420. GROSS AMOUNT DUE TO SELLER

2,771,265.33

500. REDUCTIONS IN AMOUNT TO SELLER

501. Excess Deposit (see instructions)	
502. Settlement charges to seller (line 1400)	47,244.00
503. Existing loans taken subject to	
504. Payoff of first mortgage loan	1,440,025.00
Consumer Credit Union	
505. Payoff of second mortgage loan	
506. Escrow for Repairs to Columns	34,913.00
507. Escrow for State Farm Improvements	6,000.00
508. Seller Contributions for Tenant Improvemen	20,000.00
509.	

Adjustments for items unpaid by seller

510. City/town taxes	01/01 to 07/23	7,490.99
511. County taxes	01/01 to 07/23	9,131.70
512. Assessments	to	
513. July Base Rent Due Buyer 8 Days		5,042.17
514. July CAM due Buyer 8 Days		976.06
515.		
516. Security Deposits Held		13,292.00
517.		
518.		
519.		

520. TOTAL REDUCTION AMOUNT DUE SELLER

1,584,116.00

L. SETTLEMENT CHARGES:				File Number: 20490	PAID FROM BORROWER'S FUNDS AT SETTLEMENT	PAID FROM SELLER'S FUNDS AT SETTLEMENT
700.	TOTAL SALES/BROKER'S COMMISSION based on price \$			2,771,044.00 @ 1.70 =	47,107.75	
Division of commission (line 700) as follows:						
701.	\$	47,107.75	to Mitch Cox Realtor Inc.			
702.	\$		to			
703.	Commission paid at Settlement					47,107.
704.						
800.	ITEMS PAYABLE IN CONNECTION WITH LOAN				P.O.C.	
801.	Loan Origination Fee	%	TriSummit Bank		3,000.00	
802.	Loan Discount	%				
803.	Appraisal Fee	to			4,500.00	
804.	Credit Report	to				
805.	Lender's Inspection Fee	to				
806.	Mtg. Ins. Application Fee	to				
807.	Assumption Fee	to				
808.	Phase I Environmental		Applied Environmental Services, LLC		1,425.00	
809.	Flood Certification		TriSummit Bank		14.00	
810.						
811.						
812.						
813.						
814.						
815.						
900.	ITEMS REQUIRED BY LENDER TO BE PAID IN ADVANCE					
901.	Interest from	to	@ \$	/day		
902.	Mortgage Insurance Premium		to			
903.	Hazard Insurance Premium		yrs. to			
904.						
905.						
1000.	RESERVES DEPOSITED WITH LENDER FOR					
1001.	Hazard Insurance	mo. @ \$		/ mo.		
1002.	Mortgage Insurance	mo. @ \$		/ mo.		
1003.	City property taxes	mo. @ \$		/ mo.		
1004.	County property taxes	mo. @ \$		/ mo.		
1005.	Annual Assessments	mo. @ \$		/ mo.		
1006.		mo. @ \$		/ mo.		
1007.		mo. @ \$		/ mo.		
1008.	Aggregate Reserve for Hazard/Flood Ins, City/Count					
1100.	TITLE CHARGES					
1101.	Settlement or closing fee	to	Brandt and Beeson, P.C.			
1102.	Abstract or title search	to				
1103.	Title examination	to	Brandt and Beeson, P.C.		550.00	
1104.	Title insurance binder	to	Brandt and Beeson, P.C.		30.00	
1105.	Document preparation	to	Brandt and Beeson, P.C.			75.
1106.	Notary fees	to				
1107.	Attorney's fees	to	Brandt and Beeson, P.C.		1,750.00	
	(includes above item No:)					
1108.	Title insurance	to	Brandt and Beeson/Commonwealth Land Title		4,947.25	
	(includes above item No:)					
1109.	Lender's coverage	2,216,800.00 ---	37.00			
1110.	Owner's coverage	2,771,044.00 ---	4,910.25			
1111.						
1112.	8.2 Endorsement to Policy		Brandt and Beeson/Commonwealth Land Title		100.00	
1113.						
1200.	GOVERNMENT RECORDING AND TRANSFER CHARGES					
1201.	Recording fees	Deed \$ 18.00	; Mortgage \$ 58.00	; Releases \$ 22.00	76.00	22
1202.	City/county/stamps	Deed \$; Mortgage \$			
1203.	State tax/stamps	Deed \$ 10,252.86	; Mortgage \$ 3,184.35		13,437.21	
1204.	Record Assignment of Rents and Leases				32.00	
1205.						
1300.	ADDITIONAL SETTLEMENT CHARGES					
1301.	Survey	to				
1302.	Pest inspection	to				
1303.	File UCC		Tennessee Secretary of State		30.00	
1304.	Certificate of Existence		Capital Filing Service, Inc.		40.00	40
1305.						

**B.II.E.1.--Fixed Major Medical Equipment
FDA Approval Documentation**

**B.II.E.3--Major Medical Equipment
Vendor Quotations / Draft Leases**

EQUIPMENT RENTAL TERMS AND CONDITIONS

THIS AGREEMENT made and entered into on this the 1st day of January, 2014, by and between KARING HEARTS CARDIOLOGY, PLLC, a Tennessee limited liability company, hereinafter "Lessor", and LIFESCAN LEASING, LLC, a Delaware limited liability company, hereinafter "Lessee".

WITNESSETH:

WHEREAS, Lessor owns a GE Advance NXi PET camera, hereinafter "Equipment";
and,

WHEREAS, Lessee desires to lease said Equipment.

THEREFORE, Lessor and Lessee have agreed to the following terms:

1. INITIAL RENTAL TERM AND EXTENSIONS:

(a) INITIAL TERM: This Agreement shall commence on the 1st day of February, 2014 and expire January 31, 2015, or when Lessee ceases use of the Equipment pursuant to a notification to Lessor, whichever is longer, unless a "Rental Agreement Extension" is executed, all Lessee's rights to possess and use the Equipment shall immediately cease at the end of the Term, at which time Lessor may turn off the Equipment or remove it from the Site. Lessee acknowledges its responsibility to pay for services for entire period of the initial term and subsequent extensions.

b) TERM EXTENSIONS: Term extensions must be requested by Lessee prior to the end of the existing Term. The request must specify the dates of the requested extension. The extension shall be in force once Lessee signs and returns a "Rental Agreement Extension" from Lessor. All terms and conditions of this Agreement shall remain in force during the term of the extension, except as specified in the "Rental Agreement Extension," which may include adjustments in monthly rental payments based upon utilization of Equipment.

2. PAYMENT OF RENTAL CHARGES: Lessee shall pay \$12,000.00 per month for exclusive use of the Equipment and will be billed for rental fees at the end of each calendar month. Payment is due within 30 days of the due date printed on the invoice. A late fee of 1.0% per month may be levied on unpaid balances over 30 days past the due date. Rental charges will be payable to Lessor at 701 N. State of Franklin, Ste 2, Johnson City, TN, 37604.

3. TRANSPORTATION, RISK OF LOSS, REMOVAL:

(a) Lessor shall deliver equipment to Lessee at Lessee's facilities at 701 N. State of Franklin, Suite 2, Johnson City, Tennessee. Lessor is responsible for transportation and risk of loss until the Equipment is installed at the Site. Lessee assumes responsibility for risk of loss when the equipment is installed at the site during the Term.

(b) Title to the Equipment will remain in Lessor free and clear of any lien or encumbrance of anyone other than Lessor, subject only to Lessee's right to peaceful possession and use during

the Term. Lessee agrees that the Equipment will remain personal property regardless of how it is attached to real property. Lessor may have unrestricted access to the Equipment at all reasonable times, during the Term in order to maintain it.

(c) At the end of the Term, Lessor will remove and return the Equipment at Lessor's expense including the cost of all transportation. At no time shall Lessee allow the Equipment to be permanently attached to Lessee's Site. If Lessee makes modifications to the Site or its ingress and egress which impedes the removal of the Equipment after it has been installed, the costs of removing the impediments, restoring the Site and delaying the start of the next scheduled interim rental, if applicable, will be at Lessee's expense.

(d) Lessee will return the Equipment in the same condition and appearance as when received by Lessor (reasonable wear and tear excepted), in good working order and condition and free of any bio-hazardous materials. Lessee may be billed up to \$500.00, when necessary, for removal of excessive waste and/or bio-hazardous material or patient information per the HIPAA guidelines.

4. MAINTENANCE AND REPAIR SERVICES: Lessor shall provide maintenance and repair services to the imaging system through a service contract with the Original Equipment Manufacturer (hereinafter "OEM"). The OEM or its designated affiliates will provide certain services specifically described in this section to the Equipment, within the applicable service coverage hours of OEM's standard workweek.

(a) **SPECIAL SERVICE CONDITIONS:** Subject to the availability of personnel, OEM will provide, at Lessee's request and additional expense (purchase order required), service outside the OEM's standard coverage hours. The charge for service rendered during this time will be the OEM's standard overtime rate then in effect for service contract customers with this type of Equipment including round trip travel time.

(b) **PREVENTATIVE MAINTENANCE:**

Preventative Maintenance Service is required periodically during normal business hours of 8:00.m. to 5:00 p.m. During the Term of this Agreement Lessee will make the equipment available for Preventative Maintenance, at mutually agreed upon time and date, and according to OEM requests.

5. LESSOR'S/LESSEE'S RESPONSIBILITIES:

(a) Lessor shall provide appropriate instruction manuals for the operation of the system. Lessee is responsible for providing competent personnel to operate the system. Any damage or loss resulting from operation of the system not in accordance with the instruction manuals shall be borne by Lessee.

(b) Lessor shall provide Lessee a complete set of site specifications and applicable manuals. Lessee is responsible for all site preparations in accordance with Lessee's site planning specifications.

(c) Lessee is responsible for proper screening of patients. Lessee is fully responsible for controlling access to the Equipment, and for all operations and protocols which use the Equipment or are conducted at the Site.

(d) Lessee is responsible for operating the system according to the prevailing guidelines regarding ionizing radiation and providing radiation protection to patients, as required.

(e) Lessee will provide and maintain a working phone line at the Site for Lessor's use of remote diagnostics from OEM.

(f) Lessor shall provide to Lessee a list of specifications for operation of the system. Lessee will maintain the Site and environment (including temperature and humidity control, incoming power quality, and fire protection system) in accordance with such specifications.

(g) Lessee is responsible for maintaining patient records in compliance with HIPAA guidelines. All images and patient records shall be transferred to Lessee prior to termination of this Agreement. Lessor shall not be responsible for residual patient records that reside on the system at termination of service.

6. EXCLUSIONS FROM SERVICES: OEM's maintenance and repair obligations do not cover conditions caused by:

(i) Lessee's failure to fulfill the responsibilities above;

(ii) Lessee's combining the Equipment with a product of others or with an incompatible product of OEM without Company's prior approval;

(iii) Any alteration or improper storage, handling, use or maintenance of any part of the Equipment by anyone other than OEM or its service contractor;

(iv) Anything external to the Equipment, including building structural deficiency, power surge, fluctuation or failure, and air conditioning failure.

7. OPERATING INSTRUCTION AND APPLICATION TRAINING: Lessee is responsible for operating the system properly. This Agreement does not provide for onsite applications training and the cost for such applications training, as may be requested by Lessee, shall be borne by Lessee.

8. TAXES AND PERMITS:

(a) Lessee shall also be responsible for any taxes and fees due, imposed, assessed or levied against Lessor or Lessee (or any rents or receipts hereunder), by any governmental entity or taxing authority during or related to the Term of this Agreement, including, without limitation, all license and registration fees, permits, duties and charges, together with any penalties, fines or interest thereon (collectively "Taxes"), but excluding any taxes on Lessor's revenues.

(b) Lessee is responsible for obtaining all permits, licenses and certifications necessary for siting and operating the Equipment. Lessor shall not be responsible for any penalties or sanctions levied against Lessee for its failure to obtain permits. Lessee's obligation to pay Lessor in accordance with this Agreement shall not be dependent upon Lessee's ability to obtain permits, collect accounts receivable or any other reason.

9. DELIVERY, USE AND OPERATION:

(a) Lessee agrees that the Equipment will be used by Lessee solely in the conduct of its business and in a manner complying with all applicable laws, regulations and insurance policies.

(b) Except in the event of an emergency, Lessee will not move any equipment from the Site without prior notice to Lessor.

(c) Lessee will keep the Equipment free and clear of all liens and encumbrances other than those which result from acts of Lessor.

(d) Lessor will not attach or install anything on any Equipment that will impair the originally intended function or use of such Equipment without the prior written consent of Lessee. All additions, parts, supplies, accessories, and equipment ("Additions") furnished or attached to any Equipment that are not readily removable shall become the property of Lessor.

(e) Lessee shall insure that all coils, phantoms, manuals, monitors and other removable items shall be properly stowed and returned upon surrender of the Equipment. Lessee shall be responsible for replacing all lost or missing items.

10. EXCLUSION FROM FEDERAL HEALTHCARE PROGRAMS: Lessor acknowledges that it is not, and has not been, suspended, excluded, barred or sanctioned by Medicare or any other state or federal healthcare program, nor has Lessor, nor to its knowledge, its employees or agents providing performance hereunder, ever been convicted of a criminal offense related to healthcare. Lessor shall notify Lessee promptly if any such action is proposed or taken against Lessor, or if Lessor becomes aware that such action has been taken against its employees or agents, or if Lessor becomes aware that it or its employees or agents, is the subject of an investigation that could lead to such action.

11. INSURANCE: Lessee agrees at its own expense, to keep the Equipment insured with companies acceptable to Lessor for such amounts and against such hazards as Lessor may require, including, but not limited to, all risk physical damage insurance for the Equipment itself, with losses under the policies payable to Lessor or its assigns, if any, and liability coverage for personal injuries, death and/or property damages on terms satisfactory to Lessor during the entire period the equipment is installed at the site. Said liability insurance shall be in an amount specified by Lessor, but not less than two million dollars (\$2,000,000.00). Property insurance shall be in an amount not less than (\$1,000,000.00) or such other amount that Lessor shall specify. Lessee may meet the insurance requirements of this paragraph 10 through its program of self-insurance, if existing.

12. SOFTWARE LIMITED LICENSE: Lessee agrees to comply with any "Licensed Software" Agreements between Lessor and the OEM'S, a copy of which may be found in the Operating Manuals of the system or requested from Lessor. Lessee acknowledges that the operating software on the system is proprietary and may not be copied, duplicated or dispersed without the appropriate written notification and permission from the OEM.

13. DEFAULT AND REMEDIES:

(a) Lessor may in writing declare this Agreement in default if: (i) Lessee breaches its obligation to pay rental charges or any other sum when due and fails to cure the breach within ten days after receipt of written notice from Lessee; (ii) Lessee breaches any of its insurance obligations under this Agreement; (iii) Lessee breaches any of its other obligations and fails to cure that breach within 30 days after written notice from Lessor; (iv) any representation or warranty made by Lessee in connection with this Agreement shall be false or misleading in any material respect; (v) Lessee or any guarantor or other obligor for Lessee's obligations hereunder ("Guarantor") becomes insolvent or ceases to do business as a going concern; (vi) Lessee assigns any of its interests in this Agreement or in the Equipment without Lessor's prior consent; (vii) if Lessee or any Guarantor is a natural person, any death or incompetency of Lessee or such Guarantor; (viii) a petition is filed by or against Lessee or any Guarantor under any bankruptcy or insolvency laws and in the event of an involuntary petition, the petition is not dismissed within 45 days of the filing date; or (ix) any material adverse change occurs in Lessee's financial condition or business operations (or of any Guarantor) or any material change occurs in the ownership of Lessee.

(b) Upon the occurrence of an event of default hereunder, Lessor shall have the option to do one or more of the following: (i) declare the aggregate rental charges payable under this Agreement immediately due and payable; (ii) declare all other amount(s) due Lessor hereunder immediately due and payable; (iii) collect from Lessee, on all monies due but unpaid for more than ten days, a late charge of 5.0% (five percent) each month until paid, and in addition to, the amount of all such monies, but not exceeding the lawful maximum; (iv) take possession of the Equipment and remove same from its existing location(s) with notice to Lessee; and (v) assert any other remedies available to Lessor at law or in equity (including, without limitation, under the Uniform Commercial Code). Any return and/or repossession of the Equipment shall not waive or impair any of Lessor's rights or remedies. Except as otherwise provided for herein or by law, all amount(s) due Lessor after an event of default shall be due and payable without regard to any action taken by Lessor regarding the Equipment.

(c) The foregoing remedies are cumulative, and any or all thereof may be exercised instead of or in addition to each other or any remedies at law, in equity, or under statute. Lessee shall pay Lessor's reasonable attorney's fees and other costs and expenses incurred in connection with the enforcement, assertion, defense or preservation of Lessor's rights and remedies under this Agreement, or if prohibited by law, such lesser sum as may be permitted, if Lessor is the prevailing party in any such claim.

14. LIMITATION OF REMEDIES AND DAMAGES: Lessor's liability for actual, proven damages in connection with this Agreement, whether arising under contract, tort, or any other theory of law, will not in the aggregate exceed an amount equal to Lessee's actual direct damages. In no event will Lessor be liable for any consequential, special, indirect, incidental, or

punitive loss, damage, or expense. Lessee will be barred from any remedy unless Lessee gives Lessor prompt written notice of the problem. Any claim related to this contract will be covered solely by commercial legal principles. Lessor, its representatives and Lessee will not have any negligence or other tort liability to the other arising from this Agreement. This limitation does not affect claims by third parties for personal injury due to Lessor's, its representatives or Lessee's negligence or product liability.

15. EXCUSABLE DELAYS AND PERFORMANCE ISSUES: Neither party is liable for delays or failures in performance of any obligations under this Agreement, other than payment obligations, due to a cause beyond its reasonable control.

16. MISCELLANEOUS:

(a) LESSOR AND LESSEE UNCONDITIONALLY WAIVE THEIR RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE RELATED DOCUMENTS, ANY DEALINGS BETWEEN LESSOR OR LESSEE RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED BETWEEN LESSOR AND LESSEE. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE.

(b) Time is of the essence of this Agreement. Either party's failure at any time to require strict performance by the other of any of the provisions hereof shall not waive or diminish such party's right at any other time to demand strict compliance with this Agreement. This Agreement hereto constitutes the entire Agreement of the parties with respect to the subject matter hereof. No prior proposals, statements, course of dealing or usage of trade will be a part of this Agreement. NO VARIATION OR MODIFICATION OF THIS AGREEMENT OR ANY WAIVER OF ANY OF ITS PROVISIONS OR CONDITIONS, SHALL BE VALID UNLESS IN WRITING AND SIGNED BY AN AUTHORIZED REPRESENTATIVE OF THE PARTIES HERETO.

(c) THIS AGREEMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF TENNESSEE (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE EQUIPMENT.

(d) Any cancellation or termination by Lessee, pursuant to the provisions of this Agreement or amendment hereto of the rental of any Equipment hereunder, shall not release Lessee from any then outstanding obligations to Lessor hereunder.

This Agreement constitutes the entire agreement between Lessor and Lessee, and may not be modified or amended except by a written instrument signed by both parties.

IN WITNESS WHEREOF, the parties have caused this Lease agreement to be executed by their duly authorized officers on the 11 day of October, 2013.

KARING HEARTS CARDIOLOGY, PLLC
LESSOR:

By: 

Title: Owner

LIFESCAN LEASING, LLC
LESSEE

By: 

Title: Member

B.III.--Plot Plan

SITE PLAN

SCALE: 1" = 60'-0"

TOTAL PARKING
SPACES = 118

DEEDED
ACREAGE
= 2.41

LARK STREET

CLINCHFIELD STREET

NORTH STATE OF FRANKLIN ROAD

THIS DRAWING AS PREPARED BY CAINRASHWEST ARCHITECTS
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C-1

issued 04/11/2013
drawn by BVH
project no. 00-00
drawing name
SITE PLAN

130 Regional Park Dr.
Kingsport, TN 37660
Phn (423) 349-7760
Fax (423) 349-7413
www.grcinc.com

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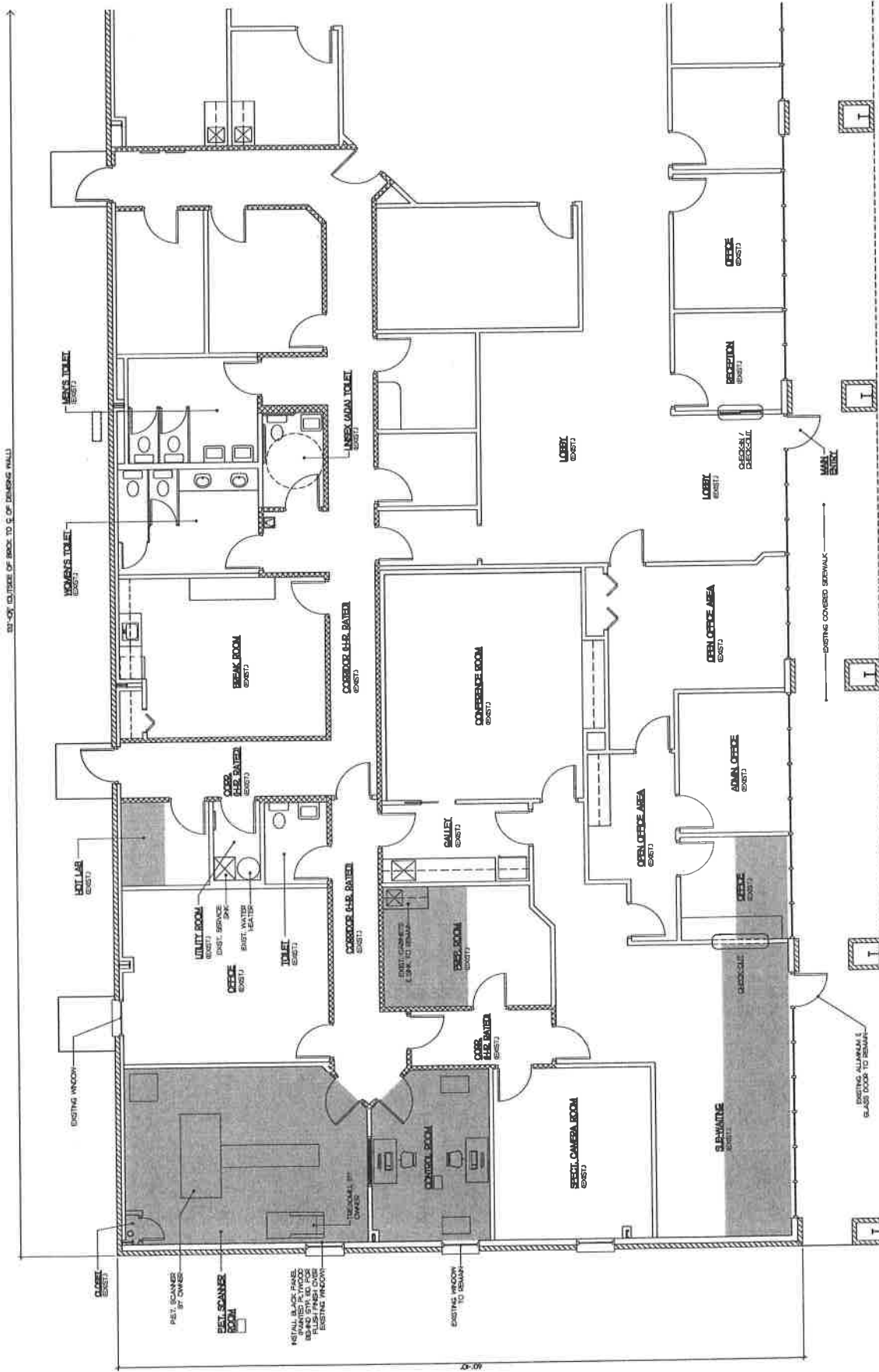
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MOLECULAR IMAGING CENTER
FOR:
LIFESCAN OF TENNESSEE







701 N. STATE OF FRANKLIN ROAD, SUITE 1
JOHNSON CITY, TENNESSEE

B.IV.--Floor Plan

REFERENCE FLOOR PLAN
SCALE: 1/4"=0'



WALL LEGEND:

	NEW WALL CONSTRUCTION
	EXISTING WALL TO REMAIN
	EXISTING - TO BE REMOVED
	EXISTING HOLE PRE-CAST WALLS
	WALLS TO BE CONVERTED TO CR
	BUILT AS HOLLOW PRE-CAST WALLS

C, Need--1.A
Documentation of Project-Specific Criteria



Medical Necessity Policy – Cardiac PET Protocol

The following protocol is prepared to insure that ordered Cardiac PET procedures are medically necessary.

Purpose:

To provide quality assurance with respect to medical necessity for cardiac PET examinations.

Protocol:

1. All requests for cardiac PET procedures must be in compliance with current Appropriate Use Criteria for PET studies published jointly, and periodically updated, by the American College of Cardiology and the American Society of Nuclear Cardiology.
2. No cardiac PET procedure will be completed without a documented request from a Karing Hearts Cardiology provider.
3. If the Clinical Director of the PET service has any concerns about the appropriateness of a PET study that has been requested, he or she shall contact the Medical Director for Cardiac PET, who will, if appropriate, contact the referring physician for discussion and confirmation of necessity, before performing the requested procedure.
4. Data will be kept and analyzed on a semiannual basis for each ordering provider and timely feedback given to all providers so that any concerns about PET utilization can be addressed.

701 N State of Franklin, Ste 2

www.karingheartscardiology.com * 423-926-4468 * fax 423-928-4838



Cardiac PET Medical Director – Job Description

Medical Director must be a licensed physician and be an authorized user of radioisotopes according to NRC or state regulatory agency regulations. The medical Director must also be an authorized user of nuclear medicine therapies.

Cardiac PET Medical Director Criteria:

- a. Board certified in cardiology
- b. Minimum of 500 independently interpreted PET cases within the previous 2 years

Cardiac PET Medical Director Responsibilities:

Responsible for all nuclear medicine services provided including quality control (QC), radiation safety, quality of care and appropriateness of care. These responsibilities include but are not limited to:

- a. The Medical Director will assume compliance with all policies/procedures/protocols and will review and update all manuals periodically as necessary (minimum every year) or as new policies are introduced. This review must be documented via signature (or initials) and date on the reviewed document or manual.
- b. Active oversight of radiation safety within the facility.
- c. The Medical Director must provide the final interpretation/report of some nuclear medicine procedures for the facility.
- d. Medical oversight, supervision and direction of the operation
- e. Responsible for the medical administrative management of Cardiac PET testing while optimizing clinical outcomes and patient satisfaction
- f. Active participation in budget management
- g. Responsible for ensuring high quality interpretive services

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- h. Responsible for the management of procedure reports and data storage systems that provide for timely results to providers as well as access to various points of care in the health system

Cardiac PET Medical Director Continuing Medical Education (CME) Requirements:

- a. The Medical Director must obtain at least 15 hours of AMA category 1 CME credits, relevant to nuclear medicine, every three years
Documentation of CME credits must be kept on file and available for inspection



CODE BLUE POLICY

PURPOSE:

To provide employees of Karing Heart's Cardiology with a plan of action in the even a patient suffers cardiopulmonary arrest. Karing Heart's Cardiology will post this CODE BLUE procedure in the following areas:

- A. PET/Nuclear Scanner room(s)
- B. ECHO/Vascular room(s)
- C. Technologist Control Room(s)
- D. Patient Foyer

PROCEDURE:

- A. The onsite supervising physician will be responsible for conducting the code and direct all CPR and resuscitation attempts.
- B. In the even there is not a physician onsite, the ACLS trained nurse or technologist will assume the responsibility of supervising the care of the patient.
 - i. Assess the patient following the American Heart Association guidelines:
 - a. Check for consciousness. If unconscious call for help, the Code Cart and make sure that 911 has been called.
 - b. Check for breathing. Initiate/support oxygenation with the ambu and oxygen tank as indicated.
 - c. Attach AED and follow prompts.
 - d. CPR will be performed when indicated by personnel trained in AHA basic life support.
- C. Staff not directly involved in caring for the patient during the emergency will maintain a calm, supportive atmosphere for any friends, family or other patients present in the facility during the emergency.
 - a. This person will also direct EMS to the back emergency door upon arrival.
- D. Continue to support the patient per AHA guidelines until EMS arrives to assume care.



- a. The supervising nurse or technologist will provide paramedics with all pertinent medical information along with a detailed report of any contrast or medications given to the patient during their test and emergency care.
- b. The patient will be transported by EMS to the nearest emergency medical facility, which will be Johnson City Medical Center, located at 400 North State of Franklin Road, Johnson City, TN.
- E. The nurse or technologist will notify the appropriate individuals of the emergency and patient disposition.
 - a. The patient's emergency contact if not present at the time of the occurrence
 - b. The patient's attending/referring physician
 - c. Karing Heart's facility manager
- F. The nurse or technologist will fully document the incident and all interventions in the patient's chart.
- G. The facility manager will monitor the patient's progress.
 - a. Contacting the physician treating the patient at the hospital where the patient is taken
 - b. Following up with the patient/and or family members
- H. The facility manager will complete the Karing Heart's Incident and Accident report.

REFERENCES:

JACHO standard
American Heart Association
ICANL Administrative protocol
IDTF policy and procedure manual

PREPARED BY: _____ **DATE:** _____

REVIEWED BY: _____ **DATE:** _____

APPROVED BY: _____ **DATE:** _____

Jeffrey W. Schoondyke MD, MPH, FACC, CCDS

212 Highland Gate Dr.
 Johnson City, TN 37601
 (H) 423-753-6655
J3schoondyke@yahoo.com

Biographical Data

Birthplace: Rock Island, Illinois (12/31/1968)

Marital Status: Married

Spouse Name: Jennifer Schoondyke

Children: Jeffrey, Age 15

Kathryn, Age 13

Kari Elizabeth, 7 months

<u>Education/Employment History</u>	<u>Degree</u>	<u>Dates of Attendance</u>
• Northern Arizona University Flagstaff, AZ	BS	8/87-5/92
• University of Oklahoma Oklahoma City, OK	MPH	8/92-5/95
• St. George's University School of Medicine Grenada, West Indies	MD	8/95-5/99
• East Tennessee State University Department of Internal Medicine Residency Program Johnson City, TN 37614		7/99-6/02
• Cardiology Fellowship East Tennessee State University Department of Cardiology Johnson City, TN 37614		7/02-6/05
• Johnson City Emergency Physicians- Contract ER Physician Johnson City Medical Center VAMC Mountain Home Tennessee Johnson County Medical Center		7/02-6/05
• Bristol Consultants, PC Bristol Regional Medical Center Bristol, TN		2/04-6/05
• Halifax Heart Center, PC Boston, VA Cardiologist		7/05-5/06
• Mountain States Medical Group Formerly Heart & Vascular Johnson City, TN Cardiologist		6/06-2/11

- Karing Hearts Cardiology, PLLC
Johnson City, TN
Cardiologist

3/2011-Present

Academic Appointments

6/06-present

- East Tennessee State University
Associate Professor of Medicine/Cardiology
James H. Quillen College of Medicine Johnson City, TN

Licensure and Boards

Date of Examination

- Board Certified Internal Medicine
- Board Certified Cardiovascular Disease
- Heart Rhythm/NASPE Certified- CCDS
- Tennessee Medical License #36563
- Virginia Medical License #0101237133
- North Carolina Medical License #2005-01437
- Current DEA Registration #BS7825790

8/2002

11/2005

9/2007

Professional Memberships

- American College of Cardiology
- American Board of Internal Medicine
- Heart Rhythm Society
- Tennessee Medical Society

Cardiovascular Skill Set

- Diagnostic Left and Right Cardiac Catheterization
- Trans-Esophageal Echocardiography
- Trans-Thoracic Echocardiography
- SPECT Perfusion Imaging Interpretation
- Cardiac PET Scanning
- DC Cardioversion
- Permanent Pacemaker Insertion
- Bi-Ventricular ICD/Pacemaker Insertion
- ICD Insertion
- IABP Insertion
- Pericardiocentesis

Presentations

- **Schoondyke Jeffrey W., MD, MPH;** Fitzpatrick Oney, D., Ph.D. Sexual Attitudes and Behaviors for a New Generation: Are They Really Changing? Slide Presentation at the Rocky Mountain Psychological Association Conference. Denver, Colorado. 1991.
- Mohan Rajesh, M.D.; Kelly Jim, Ph.D.; Ponder Michael, M.D.; **Schoondyke Jeffrey W., M.D., MPH;** Douglas John E., M.D. Fosinopril Induced Hepatotoxicity- Review of the literature and description of the first case in humans. 2001 International Experimental Biology Meeting. April 4, 2001, Orlando, Fl.

- **Schoondyke Jeffrey W., MD, MPH;** Mohan Rajesh, MD; Appakondur Sirinivasa, MD; Sandhu Dalpinder, MD; Downs Chris, MD; Bala Chidambaram, M.D.; Ponder Michael, MD, FACC. Elevated Troponin-I in a Patient With Acute Pulmonary Embolism Without Evidence of Coronary Artery Disease - A review of the literature and description of a case presenting with chest pain, acute onset shortness of breath and hypoxia. 2001 International Experimental Biology Meeting, April 4, 2001. Orlando, FL.
- **Schoondyke Jeffrey W., MD, MPH;** Baha Shabaneah, MD; Jack Whitaker, MD. Papillary Fibroelastoma of the left ventricle. Southern Medical Association National Meeting. November, 2002.
- **Schoondyke, Jeffrey W., MD, MPH.** 7th Annual Nurse Practitioner/Physician Assistant Conference for Primary Care. CHF Lecture Incorporating the New ACC Guidelines. April 1, 2003.
- **Schoondyke, Jeffrey, W. MD, MPH.** CHF Update. *Medical College of Georgia* Grand Rounds. May 2003.
- **Schoondyke, Jeffrey W. MD, MPH, FACC** Mended Hearts Monthly Meeting 3-09.
- **Schoondyke, Jeffrey W. MD, MPH, FACC.** Keynote Speaker, Mended Little Hearts Inaugural Chapter Meeting. Niswonger Children's Hospital, April 23, 2009.
- **Schoondyke, Jeffrey W. MD, MPH, FACC.** ETSU College of Medicine Annual Cardiovascular CME New Horizons Symposium. Post MI Care: An Update for Primary Care Physicians. May 2, 2009.
- **Schoondyke, Jeffrey W. MD, MPH, FACC, CCDS.** ETSU College of Medicine Annual Cardiovascular CME New Horizons Symposium. Progress in Stress Testing and Nuclear Imaging. January 25, 2013.

Research & Publications

- **Schoondyke Jeffrey W., MD, MPH;** Fitzpatrick Oney, D., Ph.D. Sexual Attitudes and Behaviors for A New Generation: Are They Really Changing? *College Student Behavior*, 1991.
- Oklahoma State Department of Health. Primary prevention for reducing firearm related morbidity and mortality. Research data collected for state health department. 1994-1995.
- Simms, J. Paul, PhD.; **Schoondyke Jeffrey, W., MD, MPH.** Use of a Personal Digital Assistant (PDA) to Monitor Vital Patient Functions in a Medical-Evacuation setting.
- **Schoondyke Jeffrey W., MD, MPH;** Hubbs Doris, MD; Ridgeway Nathan, MD, FACP. Preventable Rhabdomyolysis in Prison Inmates. *Journal of the Tennessee Medical Association*. Sept. 2001. Vol. 94. No. 9. 337-338.
- **Schoondyke Jeffrey W., MD, MPH;** Mohan Rajesh, MD; Appakondur Sirinivasa, MD; Sandhu Dalpinder, MD; Downs Chris, MD; Ponder Michael, MD, FACC. Elevated Troponin-I in a Patient With Acute Pulmonary Embolism Without Evidence of Coronary Artery Disease - Review of the literature and description of a case presenting with chest pain, acute onset shortness of breath and hypoxia. *Journal of the Tennessee Medical Association*, April 2002.
- **Schoondyke Jeffrey W., MD, MPH.** Fosinopril Induced Hepatotoxicity in a Complex Medical Patient. *Journal of the Tennessee Medical Association* May 2002.
- **Schoondyke, Jeffrey W., MD, MPH;** Burrell, Jonathan, DO.; Shabaneah, Baha, MD; Fahrig, Stephen A. MD; Whitaker, Jack, MD. Papillary Fibroelastoma involving the Left Ventricular Wall. *Cardiovascular Reviews*, 2003.

- Abi-Saleh B, Isakandar SB, **Schoondyke JW**, Fahrig, S. Tako-tsubo syndrome as a consequence of transient ischemic attack. Rev Cardiovasc Med. 2006 Winter;7(1):37-41. PMID: 1653449eb
- Mechleb BK, Kasasbeh ES, Iskandar SB, **Schoondyke JW**, Garcia ID. Mitral Valve Prolapse: Relationship of echocardiography characteristics to natural history. Echocardiography. 2006 May;23(5):434-437. PMID: 16686634
- Abi-Saleh B, **Schoondyke JW**, Abboud L, Downs CJ, Haddadin TZ, Iskandar SB. Tricuspid valve involvement in carcinoid disease. Echocardiography. 2007 Apr;24(4):439-442. PMID:17381657
- **Schoondyke, Jeffrey W., MD, MPH, FACC**; Kari's Story- Daddy's Little Girl. Voice Magazine for Women. June 2009 p.5-6.
- **Schoondyke, Jeffrey W., MD, MPH, FACC**; Physician Spotlight. East Tennessee Medical News. June 2009. Pg 5-9.
- **Schoondyke, Jeffrey W., MD, MPH, FACC**; Physician to Physician: Patients versus Process. East Tennessee Medical News. February, 2010.

Clinical Trial Research

- Principle Investigator- CURRENT Trial 2007
- Sub-PI Timi 48 Trial 2008-2009
- Medtronic Optiviol Trial 5/2009
- PI Novartis LCZ 676 Clinical Trial 3/1010

Speakers Bureau

- Boehringer Ingelheim Pharmaceuticals 2007
- Pfizer Pharmaceuticals Since 2004
- Medtronic 2007
- Molecular Imaging Alliance 2010

Honors and Scholarship

- Dean's List- Northern Arizona University, 1989-1992.
- Annual Undergraduate Research Award – Northern Arizona University 1992.
- Outstanding Psychology Student- Northern Arizona University 1992.
- Dean's List- St. George's University School of Medicine 1996-99.
- Chief Resident- Johnson City Medical Center. East Tennessee State University, Dept of Internal Medicine. 2001-2002.
- Chief of Chief Residents- East Tennessee State University College of Medicine. 2001-2002.

- ICGME Resident Representative. East Tennessee State University. 2001- 2002.
- Chief Cardiology Fellow- East Tennessee State University 2004-2005.
- Business Journal Healthcare Hero Award Recipient 2009.
- Medical Director Mountain States Medical Group- Cardiology 2009.
- Medical Director Molecular Imaging Alliance 2010.
- National Cardiology Advisor Nuclear Medicine- Molecular Imaging Alliance 2010.
- Vice-Chair Department of Cardiology Mountain States Medical Center 2012-2014.
- Most Loved Provider from Project Access 2012.

Volunteer Work

- President, Kari's Heart Foundation, Inc. A non-profit 501c3 charitable organization which provides assistance to the families of hospitalized children. 8/2008- Present.
- March of Dimes 2009 & 2010.
- Project Access: A non-profit service for underserved individuals within the healthcare system.

References Available On Request

THE
AMERICAN BOARD OF INTERNAL MEDICINE
INCORPORATED 1936
ATTESTS THAT

Jeffrey M. Schoondyke

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS HEREBY
CERTIFIED FOR THE PERIOD 2005 THROUGH 2015
AS A DIPLOMATE IN

CARDIOVASCULAR DISEASE



Troyen A. Brennan
CHAIR
AMERICAN BOARD OF INTERNAL MEDICINE

Alfred
CHAIR

Anne B. Curtis

Carl V. Lavee

Dr. Tamara
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AMERICAN BOARD OF INTERNAL MEDICINE

Guertner

Wm. G. Zuck

Barry L. Zuck

2005

Renewal No.
772510

State of Tennessee

8331114
License No.
MD0000036563

Division Of Health Related Boards

This Certifies that
JEFFREY WAYNE SCHOONDYKE, MD
whose credentials have been approved by the:
BOARD OF MEDICAL EXAMINERS
has fulfilled all requirements for renewal and registration as
required by the Tennessee Code Annotated and is a duly
authorized: MEDICAL DOCTOR
in the State of Tennessee through **DECEMBER 31, 2014**



Boemarie Otto
DIRECTOR, HEALTH RELATED BOARDS

MELANIE R DAVIDSON MD FACC

EDUCATION

2003-2006 East Tennessee State University Johnson City, Tennessee
Cardiology Fellowship

- Chief Cardiology Fellow 2005-2006

2000-2003 Cedars Sinai Medical Center Los Angeles, California
Internal Medicine Residency

- UCLA Affiliate

1996-2000 Loma Linda University Loma Linda, California
Medical School—M.D.

- Internal Medicine with Distinction
- MacKenzie Foundation Scholarship 1999

1994-1996 Loma Linda University Loma Linda, California
B.S./Clinical Laboratory Science

- Graduated with Honors
- Class Secretary 1995-1996
- Moncrieff Scholarship 1996
- Moncrieff Scholarship 1995

1992-1994 La Sierra University Riverside, California
Pre-medicine, Clinical Laboratory Science major

- Dean's List of Academic Honors

PROFESSIONAL EXPERIENCE

8/2006-Current MSMG Cardiology Kingsport,
Tennessee

Invasive Non-Interventional Cardiologist

- Cath Lab Director, Indian Path Medical Center 2008-2009

1996-1998 Riverside Community Hospital Riverside, California
Clinical Laboratory Scientist

1994-1996 Huntington East Valley Hospital Glendora, California
Laboratory Assistant

LICENSING INFORMATION

Fellow of the American College of Cardiology	2009
Board Certification for Cardiovascular disease	2006-2016
Board Certification for Internal Medicine	2003-12/2013
CA Licensing Exam for Clin. Lab. Scientist	Passed 1999
ASCP Licensing Exam	Passed 1999
TN State Medical License 37717	Exp. 7/31/14
VA State Medical License 0101237859	Exp. 7/31/14
DEA# BD9113856	Exp. 6/30/16
ACLS Certified	Exp. 1/2015

PROFESSIONAL MEMBERSHIPS

American College of Cardiology	2003-Present
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SKILLS

- Echocardiogram interpretation
- Transesophageal Echocardiogram
- Cardioversions
- Exercise stress testing
- Pharmacologic stress testing
- Nuclear imaging interpretation
- PET imaging interpretation
- Cardiac Catheterization
- ECG, Holter, and Event Monitor interpretation
- Tilt Table Testing
- Pacemaker Implantation

C, Need--1.A.3.e.
Letters of Intent

11/14/2013

Rob Gregory – Lifescan Tennessee dba Molecular Imaging Alliance
830 Suncrest Dr. Ste 2
Gray, TN 37615

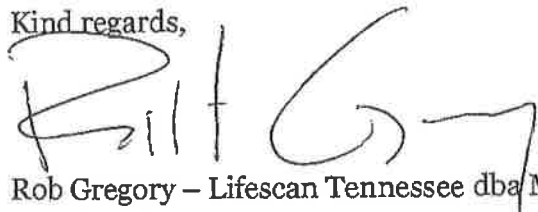
Re: CN1304-014

To whom it may concern,

Upon installation and implementation of Karing Hearts Cardiology Cardiac PET service, Lifescan Tennessee, LLC will surrender for voidance CN1304-014 that approves the relocation of existing ODC from Gray, TN to Johnson City, TN. The ODC will be closed, not be relicensed and will not seek to replace the imaging equipment.

Please let me know if further information is required.

Kind regards,

A handwritten signature in black ink, appearing to read "Rob Gregory", with a stylized flourish at the end.

Rob Gregory – Lifescan Tennessee dba Molecular Imaging Alliance
President/Owner



Precision Nuclear, LLC

October 31, 2013

Dr. Jeffrey Schoondyke
Karing Hearts Cardiology
701 N. State of Franklin, Suite 2
Johnson City, TN 37604

Dear Dr. Schoondyke:

This letter is to confirm the ability and willingness of Precision Nuclear, LLC to supply your PET imaging system at Karing Hearts Cardiology with unit dose $[N13]NH_3$ Ammonia for cardiac PET perfusion imaging for the calendar years of 2013 and 2014. Their proposed location is in Johnson City, Tennessee, should their relocation from the existing location in Gray, Tennessee, be approved by the State of Tennessee. If you have any questions or concerns, please do not hesitate to contact me directly.

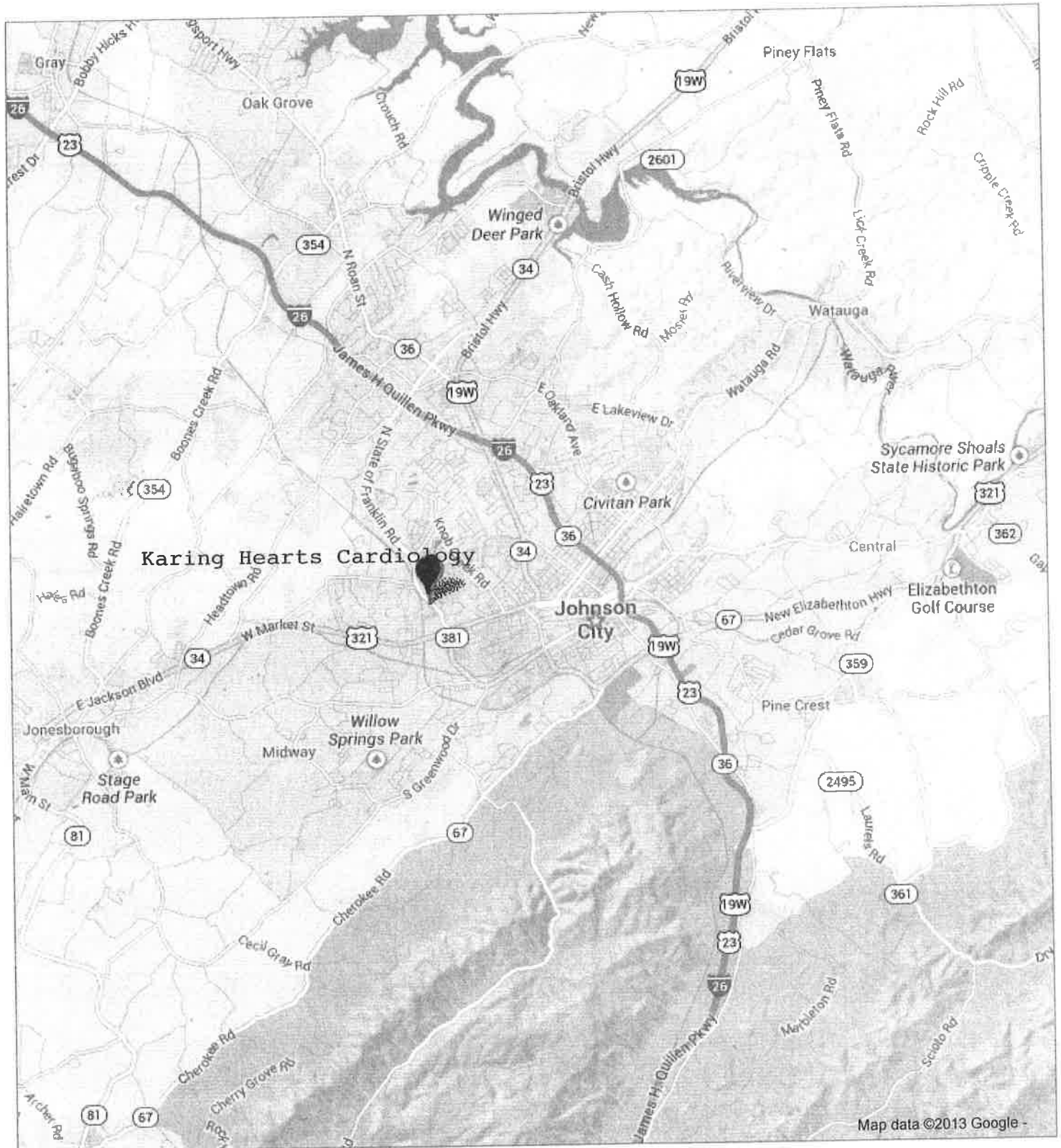
Sincerely,

Alan W. Arp, Pharm.D.
President, Precision Nuclear, LLC

C, Need--3
Service Area Maps

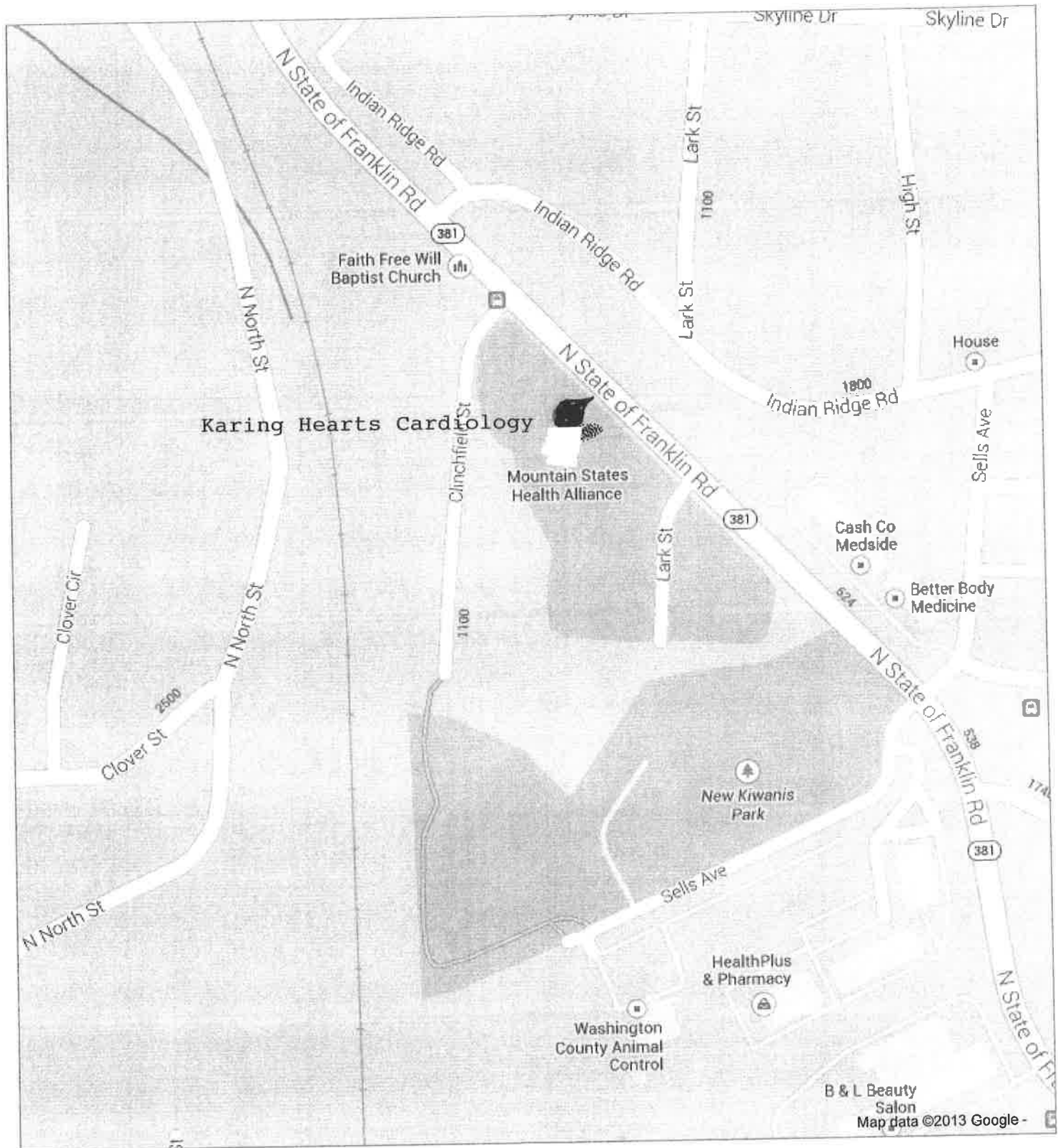
To see all the details that are visible on the screen, use the "Print" link next to the map.

Google

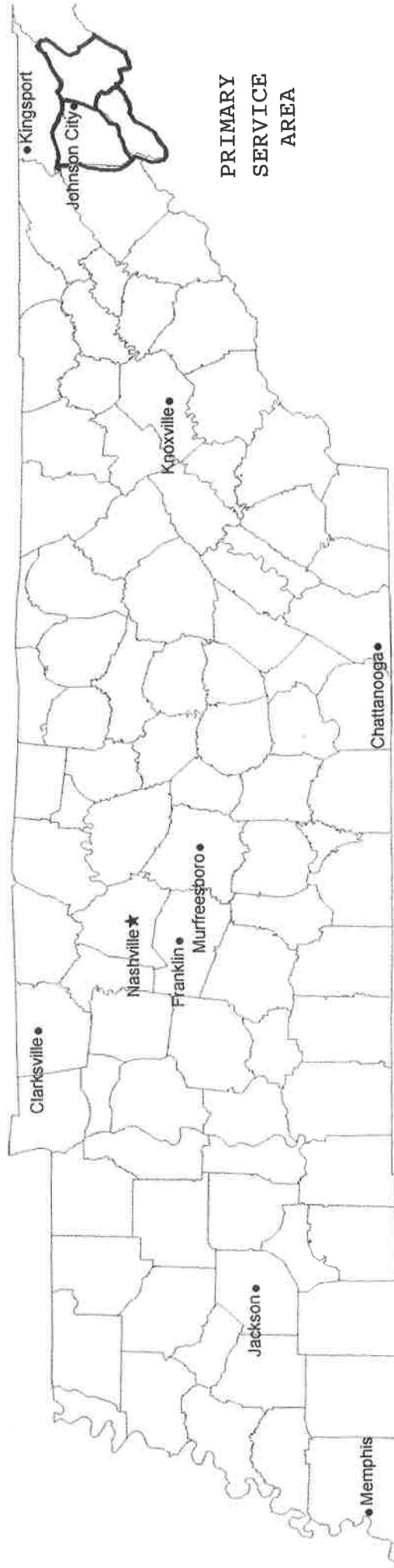


Google

To see all the details that are visible on the screen, use the "Print" link next to the map.

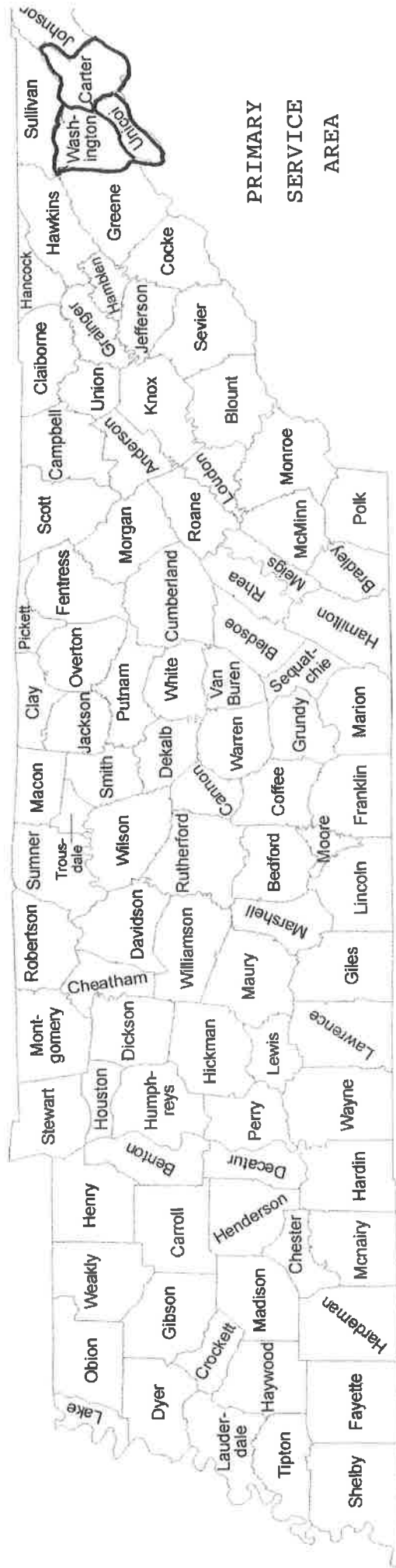


Karing Hearts Cardiology Cardiac PET Service



Get Printable Maps From:
Waterproof Paper.com

Karing Hearts Cardiology Cardiac PET Service



Get Printable Maps From:
WaterproofPaper.com

C, Economic Feasibility--1
Documentation of Construction Cost Estimate



MITCH COX
COMPANIES

November 12, 2013

Mr. Rob Gregory
Karing Hearts Cardiology
701 N. State of Franklin Road, Suite 2
Johnson City, TN 37604

Subject: Verification of Construction Cost Estimate
Installation of P.E.T. Imaging System
Johnson City, Tennessee

Rob,

I have reviewed the cost data for the above-referenced project, for which our firm has provided a preliminary design. The stated renovation construction cost is approximately \$100,000.00 [In providing opinions of probable construction cost, the Client understands that the Consultant has no control over the cost or availability of labor, equipment or materials, or over market conditions of the selected contractor's method of pricing, and that the Consultant's opinions of probable construction costs are made on the basis of the Consultant's professional judgment and experience. The Consultant makes no warranty, express or implied, that the bids or negotiated cost of the work will not vary from the Consultant's opinion of probable construction cost.]

It is our opinion that at this time, the projected renovated construction cost is reasonable for this type and size of project and compares appropriately with similar projects in this market.

The current building codes applicable to the project, as of the date of this letter, will be;

- 2006 International Building Codes (Bldg., Mechanical, Gas, Etc.)
- 2006 National Fire Protection Association Codes (including Life Safety Code)
- 2002 North Carolina Accessibility Code with 2004 amendments.
- National Electric Code
- Americans with Disabilities Act (ADA)

This listing is not entirely inclusive, but the intent is for all applicable codes and standards, State and local, to be addressed during the design process. The codes in effect at the time of submittal of plans and specifications shall be the codes to be used throughout the project.

Sincerely,

Michael J Cannon

Architect, TN License #17,125

O 423.282.6582
F 423.282.5903
www.mitchcox.com

801 Sunset Drive, Suite D-1
Johnson City, TN 37604

C, Economic Feasibility--2
Documentation of Availability of Funding



November 12, 2013

Melanie M. Hill, Executive Director
Tennessee Health Services and Development Agency
Frost Building, Third Floor
161 Rosa Parks Boulevard
Nashville, Tennessee 37203

RE: Karing Hearts Cardiology, PLLC

Dear Ms. Hill:

This letter is to provide assurance that Mountain Commerce Bank is familiar with the subject project, which is being proposed by Karing Hearts Cardiology.

Upon submittal and approval of a formal financing application, we would expect to be able to provide both construction and permanent financing for this project. We understand that the financing required would total \$139,000.00 of initial funding.

The loan package on this project would of course reflect market conditions at the time of loan approval. Currently we would expect to finance this type of project at an interest rate of approximately 4.75% for a term of 10 Years. Attached is an amortization schedule reflecting that estimate.

We look forward to helping with the financing of this project.

Sincerely,

Bobby A. Brown
Senior Vice President

3122 Bristol Highway Johnson City TN 37601
PH: 423-232-5002

Date: 11/14/13

Mountain Commerce Bank

Page: 1

Prepared for Xairing Hearts Cardio
Platform Type CR
Account #

Officer BAB
Rate 4.75000% Payment
APR 4.8173% Interest

1,461.92
36,430.50

CSR S67BROWN
Term 120

Payment Day:

Date	Number	Misc.	Interest	Payment	Principal	PMT Int.	Total	Balance
12/18/13	1	.00	550.21	550.21	911.71	.00	Original Balance 1,461.92	139,000.00
Year 2013		.00	550.21		911.71	.00	1,461.92	138,088.29
1/18/14	2	.00	564.82	564.82	897.10	.00	1,461.92	137,191.19
2/18/14	3	.00	561.15	561.15	900.77	.00	1,461.92	136,290.42
3/18/14	4	.00	503.52	503.52	958.40	.00	1,461.92	135,332.02
4/18/14	5	.00	553.54	553.54	908.38	.00	1,461.92	134,423.64
5/18/14	6	.00	532.09	532.09	929.83	.00	1,461.92	133,493.81
6/18/14	7	.00	546.03	546.03	915.89	.00	1,461.92	132,577.92
7/18/14	8	.00	524.79	524.79	937.13	.00	1,461.92	131,640.79
8/18/14	9	.00	538.45	538.45	923.47	.00	1,461.92	130,717.32
9/18/14	10	.00	534.67	534.67	927.25	.00	1,461.92	129,790.07
10/18/14	11	.00	513.75	513.75	948.17	.00	1,461.92	128,841.90
11/18/14	12	.00	527.00	527.00	934.92	.00	1,461.92	127,906.98
12/18/14	13	.00	506.30	506.30	955.62	.00	1,461.92	126,951.36
Year 2014		.00	6,406.11		11,136.93	.00	17,543.04	
1/18/15	14	.00	519.26	519.26	942.66	.00	1,461.92	126,008.70
2/18/15	15	.00	515.41	515.41	946.51	.00	1,461.92	125,062.19
3/18/15	16	.00	462.04	462.04	999.88	.00	1,461.92	124,062.31
4/18/15	17	.00	507.45	507.45	954.47	.00	1,461.92	123,107.84
5/18/15	18	.00	487.30	487.30	974.62	.00	1,461.92	122,133.22
6/18/15	19	.00	499.56	499.56	962.36	.00	1,461.92	121,170.86
7/18/15	20	.00	479.63	479.63	982.28	.00	1,461.92	120,188.57
8/18/15	21	.00	491.61	491.61	970.31	.00	1,461.92	119,218.26
9/18/15	22	.00	487.63	487.63	974.29	.00	1,461.92	118,243.97
10/18/15	23	.00	468.05	468.05	993.87	.00	1,461.92	117,250.10
11/18/15	24	.00	479.59	479.59	982.33	.00	1,461.92	116,267.77
12/18/15	25	.00	460.22	460.22	1,001.70	.00	1,461.92	115,266.07
Year 2015		.00	5,857.75		11,685.29	.00	17,543.04	
1/18/16	26	.00	471.47	471.47	990.45	.00	1,461.92	114,275.62
2/18/16	27	.00	467.42	467.42	994.50	.00	1,461.92	113,281.12
3/18/16	28	.00	433.46	433.46	1,028.46	.00	1,461.92	112,252.66
4/18/16	29	.00	459.15	459.15	1,002.77	.00	1,461.92	111,249.89
5/18/16	30	.00	440.36	440.36	1,021.56	.00	1,461.92	110,228.33
6/18/16	31	.00	450.86	450.86	1,011.06	.00	1,461.92	109,217.27
7/18/16	32	.00	432.32	432.32	1,029.60	.00	1,461.92	108,187.67
8/18/16	33	.00	442.52	442.52	1,019.40	.00	1,461.92	107,168.27
9/18/16	34	.00	438.35	438.35	1,023.57	.00	1,461.92	106,144.70
10/18/16	35	.00	420.15	420.15	1,041.77	.00	1,461.92	105,102.93
11/18/16	36	.00	429.91	429.91	1,032.01	.00	1,461.92	104,070.92
12/18/16	37	.00	411.94	411.94	1,049.98	.00	1,461.92	103,020.94
Year 2016		.00	5,297.91		12,245.13	.00	17,543.04	

C, Economic Feasibility--10
Financial Statements

Charles F. Bolton, (1928-2008)

Kimberly D. Coker, CPA

Gregory M. DeGennaro, CPA



Members
American Institute and
Tennessee Society of
Certified Public Accountants

To the Owner
Karing Hearts Cardiology, PLLC
Johnson City, TN

We have compiled the accompanying balance sheet of Karing Hearts Cardiology, LLC (a sole proprietorship) as of October 31, 2013 and related statement of income for the ten months then ended. We have not audited or reviewed the accompanying financial statements and, accordingly, do not express an opinion or provide any assurance about whether the financial statements are in accordance with accounting principles generally accepted in the United States of America.

The owner is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America and for designing, implementing, and maintaining internal control relevant to the preparation and fair presentation of the financial statements.

Our responsibility is to conduct the compilation in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants. The objective of a compilation is to assist the owner in presenting financial information in the form of financial statements without undertaking to obtain or provide any assurance that there are no material modifications that should be made to the financial statements.

The owner has elected to omit substantially all the disclosures and the statements of proprietor's capital and cash flows required by accounting principles generally accepted in the United States of America. If the omitted disclosures and statements of proprietor's capital and cash flows were included in the financial statements, they might influence the user's conclusions about the Company's financial position, result of operations, and cash flows. Accordingly, the financial statements are not designed for those who are not informed about such matters.

Bolton, Coker and DeGennaro, CPAs, P.C.

November 5, 2013

11/11/13
Cash Basis

Karing Hearts Cardiology, PLLC
Balance Sheet
As of October 31, 2013

	Oct 31, 13
ASSETS	
Current Assets	
Checking/Savings	
Bank of Tennessee	36,968.03
Bank of TN - EFT	132.16
Mountain Commerce - Dental	2,948.66
Mountain Commerce Bank-Investme	4,750.00
Mountain Commerce Bank - Oper	15,118.30
Petty Cash	2,769.00
Total Checking/Savings	62,686.15
Other Current Assets	
Employee Loan	250.00
Loan Rec. - Genesis	9,734.00
Total Other Current Assets	9,984.00
Total Current Assets	72,670.15
Fixed Assets	
Accumulated Depreciation	-85,871.00
Building	22,211.17
Furniture and Equipment	119,057.98
Leasehold Improvements	117,919.92
Medical Equipment	78,434.90
Total Fixed Assets	251,752.97
Other Assets	
Accumulated Amortization	-2,567.00
Loan Costs	3,579.86
Organization Costs	22,000.00
Total Other Assets	23,012.86
TOTAL ASSETS	347,435.98
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Accounts Payable	
Accounts Payable	4,742.57
Total Accounts Payable	4,742.57
Other Current Liabilities	
Bank of Tennessee - LOC	20,000.00
Payroll Liabilities	
After Tax Dental Fund	2,849.36
Employee Benefits	
Section 125 - Health Insurance	1,561.76
Total Employee Benefits	1,561.76
Payroll Taxes	
FUTA Company	56.77
SUTA Company	312.32
Virginia Income Tax W/H	176.00
Total Payroll Taxes	545.09
Payroll Liabilities - Other	4,750.00
Total Payroll Liabilities	9,706.21
Total Other Current Liabilities	29,706.21
Total Current Liabilities	34,448.78

11/11/13
Cash Basis

Karing Hearts Cardiology, PLLC
Balance Sheet
As of October 31, 2013

	Oct 31, 13
Long Term Liabilities	
Bank of TN - Capital Loan	325,543.86
Total Long Term Liabilities	325,543.86
Total Liabilities	359,992.64
Equity	
Members Equity	-123,492.49
Net Income	110,935.83
Total Equity	-12,556.66
TOTAL LIABILITIES & EQUITY	347,435.98

11/11/13
Cash Basis

Karing Hearts Cardiology, PLLC
Profit & Loss
January through October 2013

	Jan - Oct 13
Ordinary Income/Expense	
Income	
Practice Receipts	1,470,138.46
Refunds	-1,100.03
Total Income	1,469,038.43
Gross Profit	1,469,038.43
Expense	
Advertising and Promotion	12,452.59
Answering Service	1,654.79
Automobile Expense	170.59
Bank Service Charges	2,302.97
Billing Fees	22,937.03
Business Gifts	49.22
Business Licenses and Permits	150.00
Charitable Donations	14,491.62
Clinical Supplies	29,416.11
Computer and Internet Expenses	27,113.96
Continuing Education	3,301.22
Contractual Services	
Echo Technician	5,302.56
Interpreter	110.17
Contractual Services - Other	1,250.00
Total Contractual Services	6,662.73
Dues and Memberships	4,306.27
Equipment Rental	1,555.61
Insurance Expense	
Business and Property	696.90
Life Insurance	1,407.16
Malpractice Insurance	19,311.00
Total Insurance Expense	21,415.06
Interest Expense	12,925.33
Janitorial Expense	8,555.52
Laboratory Fees	673.25
Meals and Entertainment	17,085.23
Office Supplies	21,633.33
Payroll Expenses	
Employee Benefits	
Health Insurance	30,703.46
Total Employee Benefits	30,703.46
Employee Salaries and Wages	
Employee Salaries	216,456.25
Employee Wages	250,686.59
Total Employee Salaries and Wages	467,142.84
Payroll Taxes	
Federal Unemployment	666.91
FICA - Medicare	11,665.65
FICA - Social Security	35,293.42
TN Unemployment	3,759.92
Total Payroll Taxes	51,385.90
Payroll Expenses - Other	2,211.55
Total Payroll Expenses	551,443.75
Postage and Shipping	2,439.70
Printing	1,809.54
Processing Fees	1,199.30
Professional Fees	
Accounting Services	12,780.00

11/11/13
Cash Basis

Karing Hearts Cardiology, PLLC
Profit & Loss
January through October 2013

	Jan - Oct 13
Total Professional Fees	12,780.00
Rent Expense	47,464.59
Repairs and Maintenance	12,734.99
Retirement Plan Administration	1,224.00
Security Expense	563.80
Small Medical Equipment	1,639.43
Taxes	
Franchise/Excise	2,022.00
Professional Privilege	1,970.00
Total Taxes	3,992.00
Telephone Expense	10,901.51
Travel Expense	7,651.84
Uniforms	1,520.56
Uniforms/Clothing	208.87
Utilities	
Electricity	17,291.15
Gas	2,205.14
Total Utilities	19,496.29
Total Expense	885,922.60
Net Ordinary Income	583,115.83
Other Income/Expense	
Other Expense	
Owner Draws	119,900.00
Owner Salary	352,280.00
Total Other Expense	472,180.00
Net Other Income	-472,180.00
Net Income	110,935.83

Karing Hearts Cardiology, PLLC
Balance Sheet
As of December 31, 2012

Cash Basis

	Dec 31, 12
ASSETS	
Current Assets	
Checking/Savings	
Bank of Tennessee	13,808.73
Mountain Commerce - Dental	2,148.66
Mountain Commerce Bank - Oper	20,161.30
Petty Cash	2,519.00
Total Checking/Savings	38,637.69
Total Current Assets	38,637.69
Fixed Assets	
Accumulated Depreciation	-85,871.00
Furniture and Equipment	114,423.32
Leasehold Improvements	66,894.60
Total Fixed Assets	95,446.92
Other Assets	
Accumulated Amortization	-2,567.00
Organization Costs	22,000.00
Total Other Assets	19,433.00
TOTAL ASSETS	153,517.61
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Accounts Payable	
Accounts Payable	1,246.76
Total Accounts Payable	1,246.76
Other Current Liabilities	
Payroll Liabilities	
After Tax Dental Fund	2,049.36
Employee Benefits	
Section 125 - Health Insurance	800.72
Total Employee Benefits	800.72
Payroll Taxes	
FUTA Company	50.26
SUTA Company	311.60
Virginia Income Tax W/H	156.00
Total Payroll Taxes	517.86
Payroll Liabilities - Other	170.00
Total Payroll Liabilities	3,537.94
Total Other Current Liabilities	3,537.94
Total Current Liabilities	4,784.70
Long Term Liabilities	
Bank of TN - Capital Loan	272,225.40
Total Long Term Liabilities	272,225.40
Total Liabilities	277,010.10
Equity	
Members Draw	-59,443.96
Members Equity	-101,175.51
Net Income	37,126.98
Total Equity	-123,492.49
TOTAL LIABILITIES & EQUITY	153,517.61

Karing Hearts Cardiology, PLLC
Profit & Loss
January through December 2012

Cash Basis

	Jan - Dec 12
Ordinary Income/Expense	
Income	
Practice Receipts	1,380,638.22
Refunds	-1,261.32
Total Income	1,379,376.90
Gross Profit	1,379,376.90
Expense	
Advertising and Promotion	22,954.31
Amortization Expense	1,467.00
Answering Service	2,136.30
Bank Service Charges	2,480.48
Billing Fees	39,788.29
Books and Manuals	173.16
Business Gifts	120.00
Charitable Donations	15,365.20
Clinical Supplies	12,360.31
Computer and Internet Expenses	4,245.41
Continuing Education	2,085.00
Contractual Services	7,380.00
Depreciation Expense	77,965.00
Dues and Memberships	8,673.40
Insurance Expense	
Business and Property	599.00
Malpractice Insurance	14,614.00
Insurance Expense - Other	3,143.89
Total Insurance Expense	18,356.89
Interest Expense	17,130.43
Janitorial Expense	1,500.00
Laboratory Fees	318.25
Leasehold Imp Abandonment	28,253.00
Meals and Entertainment	6,245.37
Office Supplies	37,059.04
Payroll Expenses	
Employee Benefits	
Employee Relocation Expense	3,219.00
Health Insurance	25,141.02
Total Employee Benefits	28,360.02
Employee Salaries and Wages	
Employee Salaries	286,172.21
Employee Wages	220,164.22
Total Employee Salaries and Wages	506,336.43
Payroll Taxes	
Federal Unemployment	616.56
FICA - Medicare	11,686.28
FICA - Social Security	35,740.33
TN Unemployment	3,414.50
Total Payroll Taxes	51,457.67
Payroll Expenses - Other	1,029.94
Total Payroll Expenses	587,184.06
Postage and Shipping	909.19
Printing	1,537.12
Processing Fees	1,600.00
Professional Fees	
Accounting Services	7,495.00
Legal Fees	14,900.00
Professional Fees - Other	3,584.00
Total Professional Fees	25,979.00

Karing Hearts Cardiology, PLLC
Profit & Loss
January through December 2012

Cash Basis

	Jan - Dec 12
Rent Expense	37,021.04
Repairs and Maintenance	10,391.96
Retirement Plan Administration	1,224.00
Taxes	
Franchise/Excise	575.00
Professional Privilege	400.00
Total Taxes	975.00
Telephone Expense	18,076.88
Travel Expense	8,644.89
Uniforms	231.02
Uniforms/Clothing	4,179.96
Utilities	
Cable and Internet	6,961.54
Electricity	6,822.99
Gas	892.89
Total Utilities	14,677.42
Total Expense	1,018,688.38
Net Ordinary Income	360,688.52
Other Income/Expense	
Other Expense	
Owner Salary	323,561.54
Total Other Expense	323,561.54
Net Other Income	-323,561.54
Net Income	37,126.98

Miscellaneous Information

Midmonth Report for July 2013

- * This report is a count of people taken in the middle of the month for which the report was run.
- * This report is run three months after the month of the report in an effort to reduce fluctuations in the results.

MCO	REGION	Total
Awaiting MCO assignment		307
AMERIGROUP COMMUNITY CARE	Middle Tennessee	195,036
BLUECARE	East Tennessee	211,451
BLUECARE	West Tennessee	175,903
TENNCARE SELECT	All	45,559
UnitedHealthcare Community Plan	East Tennessee	194,264
	Middle Tennessee	198,106
	West Tennessee	173,095
Grand Total		1,193,721

COUNTY	Female			Male			Grand Total
	0 - 18	19 - 20	21 - 64	65 ->	0 - 18	19 - 20	
ANDERSON	3,770	286	3,257	605	7,918	3,931	13,899
BEDFORD	3,332	226	2,226	266	6,050	3,437	10,668
BENTON	920	86	794	148	1,948	1,021	3,528
BLEDSE	721	61	620	124	1,527	834	2,820
BLOUNT	5,217	411	4,392	664	10,683	5,274	18,538
BRADLEY	4,884	407	4,319	634	10,244	5,267	17,942
CAMPBELL	2,695	242	3,045	652	6,635	2,765	11,633
CANNON	680	52	633	126	1,491	756	2,627
CARROLL	1,649	164	1,584	329	3,726	1,843	6,651
CARTER	2,931	220	2,575	704	6,430	3,072	11,282
CHEATHAM	1,773	135	1,389	183	3,480	1,828	6,154
CHESTER	936	86	796	150	1,968	959	3,403
CLAIBORNE	1,816	158	1,858	537	4,369	1,912	7,814
CLAY	498	35	405	105	1,044	488	1,908
COCKE	2,569	216	2,362	449	5,596	2,611	9,932
COFFE	3,142	204	2,683	386	6,416	3,187	11,065
CROCKETT	983	75	728	211	1,998	933	3,405
CUMBERLAND	2,812	214	2,278	500	5,804	2,980	10,346
DAVIDSON	36,133	2,348	27,066	3,180	68,727	37,171	119,305
DECATUR	561	61	519	195	1,336	659	2,410
DEKALB	1,181	68	1,006	191	2,446	1,245	4,380
DICKSON	2,523	162	2,142	307	5,124	2,678	8,899
DYER	2,511	241	2,215	429	5,395	2,584	9,255
FAYETTE	1,546	132	1,173	298	3,150	1,697	5,604
FENTRESS	1,241	120	1,236	382	2,979	1,358	5,411
FRANKLIN	1,723	156	1,511	266	3,656	1,773	6,327
GIBSON	2,911	254	2,684	616	6,464	3,079	11,196
GILES	1,410	125	1,229	247	3,011	1,413	5,204
GRAINGER	1,282	102	1,085	288	2,766	1,290	4,964
GREENE	3,197	236	3,060	725	7,218	3,323	12,695

GRUNDY	1,054	99	1,040	226	2,419	1,153	69	598	137	1,958	4,377
HAMBLETON	4,004	241	2,739	537	7,522	4,038	150	1,228	224	5,639	13,161
HAMILTON	15,275	1,141	13,220	2,226	31,862	15,925	780	5,303	859	22,866	54,728
HANCOCK	476	50	518	185	1,208	540	42	303	78	962	2,170
HARDEMAN	1,609	134	1,491	339	3,573	1,590	83	742	158	2,573	6,146
HARDIN	1,583	131	1,463	394	3,570	1,590	108	801	197	2,697	6,287
HAWKINS	3,008	271	2,787	561	6,627	3,161	169	1,421	255	5,005	11,532
HAYWOOD	1,412	126	1,330	295	3,163	1,476	99	432	106	2,113	5,276
HENDERSON	1,636	133	1,471	272	3,512	1,694	87	645	99	2,525	6,036
HENRY	1,909	154	1,599	282	3,944	1,990	134	755	117	2,896	6,940
HICKMAN	1,351	133	1,191	188	2,863	1,486	107	645	81	2,319	5,182
HOUSTON	407	28	370	108	913	451	24	198	76	754	1,667
HUMPHREYS	947	84	806	159	1,997	1,012	41	388	68	1,508	3,505
JACKSON	623	44	595	147	1,409	657	28	344	93	1,121	2,531
JEFFERSON	2,769	189	2,149	496	5,603	2,904	128	1,104	203	4,339	9,942
JOHNSON	938	89	864	295	2,186	964	53	562	154	1,734	3,920
KNOX	17,337	1,221	15,400	2,372	36,329	18,023	833	6,594	979	26,429	62,758
LAKE	409	45	507	156	1,117	507	34	217	71	830	1,947
LAUDERDALE	1,905	151	1,745	314	4,115	1,943	119	711	121	2,894	7,009
LAWRENCE	2,262	197	1,908	416	4,782	2,494	144	888	167	3,693	8,475
LEWIS	700	70	573	119	1,462	737	51	252	57	1,097	2,559
LINCOLN	1,716	151	1,362	296	3,525	1,844	106	683	114	2,747	6,272
LOUDON	2,074	131	1,478	279	3,962	2,113	95	691	118	3,017	6,980
MACON	1,625	131	1,307	250	3,313	1,700	79	689	111	2,579	5,892
MADISON	5,882	479	5,350	831	12,542	5,876	316	1,865	328	8,385	20,927
MARION	1,638	157	1,568	251	3,614	1,661	101	667	134	2,563	6,177
MARSHALL	1,582	115	1,263	170	3,130	1,649	78	540	73	2,340	5,470
MAURY	4,155	284	3,398	557	8,394	4,474	207	1,314	181	6,175	14,569
MCMINN	2,809	216	2,433	515	5,973	2,888	144	1,108	221	4,362	10,334
MCNAIRY	1,691	149	1,630	390	3,860	1,760	116	898	191	2,966	6,826
MEIGS	712	52	603	87	1,454	728	53	325	44	1,151	2,606
MONROE	2,520	226	2,239	507	5,492	2,812	129	1,193	261	4,395	9,886
MONTGOMERY	6,938	530	5,612	653	13,732	7,149	307	1,810	208	9,475	23,206
MOORE	218	20	153	44	435	257	9	89	17	372	807
MORGAN	1,161	78	908	187	2,334	1,207	61	509	112	1,889	4,223
OBION	1,756	138	1,587	297	3,778	1,876	87	606	110	2,678	6,456
OVERTON	1,134	90	947	269	2,441	1,226	74	541	140	1,981	4,421
PERRY	509	33	381	85	1,009	527	30	228	44	829	1,838
PICKETT	230	20	206	87	543	281	10	131	44	466	1,009
POLK	895	52	830	157	1,934	976	56	441	68	1,541	3,475
PUTNAM	3,721	356	3,179	753	8,009	3,868	223	1,687	314	6,093	14,102
RHEA	2,202	155	1,772	326	4,455	2,237	120	843	126	3,326	7,782
ROANE	2,319	205	2,333	530	5,387	2,625	123	1,284	224	4,255	9,642
ROBERTSON	3,373	174	2,273	366	6,186	3,552	133	894	164	4,744	10,930
RUTHERFORD	11,201	890	7,830	958	20,878	11,602	530	2,790	382	15,304	36,182
SCOTT	1,777	141	1,677	398	3,994	1,833	110	936	191	3,069	7,063
SEQUATCHIE	909	82	763	149	1,904	941	54	417	58	1,470	3,373
SEVIER	4,593	330	3,090	458	8,471	4,984	168	1,249	164	6,564	15,035
SHELBY	68,080	5,779	54,837	6,583	135,280	69,588	4,143	16,143	2,496	92,370	227,849
SMITH	1,018	75	865	174	2,130	1,017	47	406	64	1,534	3,665
STEWART	588	42	615	113	1,409	684	31	294	56	1,055	2,473

SULLIVAN	6,986	580	6,647	1,336	15,549	7,429	404	3,344	586	11,764	27,313
SUMNER	6,641	510	5,296	784	13,232	7,015	374	2,020	307	9,715	22,947
TIPTON	3,382	295	2,634	362	6,673	3,545	196	949	148	4,838	11,511
TROUSDALE	492	26	388	83	989	439	37	194	36	706	1,695
UNICOI	876	50	785	274	1,985	980	43	369	130	1,521	3,505
UNION	1,304	90	921	158	2,473	1,295	63	522	83	1,963	4,436
VAN BUREN	278	25	269	61	633	308	11	152	44	515	1,148
WARREN	2,553	178	2,101	430	5,261	2,644	142	1,036	184	4,006	9,267
WASHINGTON	4,866	408	4,779	966	11,019	5,079	282	2,231	392	7,985	19,004
WAYNE	734	56	632	173	1,595	797	44	332	71	1,245	2,939
WEAKLEY	1,658	215	1,489	322	3,684	1,709	117	713	110	2,649	6,333
WHITE	1,545	127	1,342	333	3,347	1,672	101	755	118	2,647	5,994
WILLIAMSON	2,561	159	1,679	341	4,740	2,701	111	676	117	3,605	8,345
WILSON	4,226	326	3,420	498	8,470	4,408	189	1,400	178	6,176	14,646
Grand Total	336,351	26,327	279,504	46,809	688,991	349,669	18,347	116,937	19,776	504,730	1,193,721

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State & County QuickFacts

Washington County, Tennessee

People QuickFacts	Washington County	Tennessee
Population, 2012 estimate	125,094	6,456,243
Population, 2010 (April 1) estimates base	122,979	6,346,113
Population, percent change, April 1, 2010 to July 1, 2012	1.7%	1.7%
Population, 2010	122,979	6,346,105
Persons under 5 years, percent, 2012	5.3%	6.3%
Persons under 18 years, percent, 2012	19.8%	23.1%
Persons 65 years and over, percent, 2012	16.0%	14.2%
Female persons, percent, 2012	51.1%	51.2%
White alone, percent, 2012 (a)	92.6%	79.3%
Black or African American alone, percent, 2012 (a)	4.1%	17.0%
American Indian and Alaska Native alone, percent, 2012 (a)	0.4%	0.4%
Asian alone, percent, 2012 (a)	1.3%	1.6%
Native Hawaiian and Other Pacific Islander alone, percent, 2012 (a)	Z	0.1%
Two or More Races, percent, 2012	1.6%	1.6%
Hispanic or Latino, percent, 2012 (b)	3.1%	4.8%
White alone, not Hispanic or Latino, percent, 2012	90.0%	75.1%
Living in same house 1 year & over, percent, 2007-2011	82.9%	84.1%
Foreign born persons, percent, 2007-2011	3.4%	4.5%
Language other than English spoken at home, percent age 5+, 2007-2011	4.6%	6.4%
High school graduate or higher, percent of persons age 25+, 2007-2011	85.1%	83.2%
Bachelor's degree or higher, percent of persons age 25+, 2007-2011	28.2%	23.0%
Veterans, 2007-2011	11,873	501,665
Mean travel time to work (minutes), workers age 16+, 2007-2011	19.9	24.0
Housing units, 2011	57,962	2,829,025
Homeownership rate, 2007-2011	66.4%	69.0%
Housing units in multi-unit structures, percent, 2007-2011	21.8%	18.1%
Median value of owner-occupied housing units, 2007-2011	\$142,900	\$137,200
Households, 2007-2011	50,523	2,457,997
Persons per household, 2007-2011	2.32	2.50
Per capita money income in the past 12 months (2011 dollars), 2007-2011	\$24,742	\$24,197
Median household income, 2007-2011	\$42,104	\$43,989
Persons below poverty level, percent, 2007-2011	17.3%	16.9%
Business QuickFacts	Washington County	Tennessee
Private nonfarm establishments, 2011	2,814	129,489 ¹
Private nonfarm employment, 2011	49,087	2,300,542 ¹
Private nonfarm employment, percent change, 2010-2011	-0.3%	1.6% ¹
Nonemployer establishments, 2011	7,696	473,451
Total number of firms, 2007	10,153	545,348
Black-owned firms, percent, 2007	2.0%	8.4%
American Indian- and Alaska Native-owned firms, percent, 2007	F	0.5%
Asian-owned firms, percent, 2007	S	2.0%
Native Hawaiian and Other Pacific Islander-owned firms,		

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State & County QuickFacts

Carter County, Tennessee

People QuickFacts	Carter County	Tennessee
Population, 2012 estimate	57,355	6,456,243
Population, 2010 (April 1) estimates base	57,424	6,346,113
Population, percent change, April 1, 2010 to July 1, 2012	-0.1%	1.7%
Population, 2010	57,424	6,346,105
Persons under 5 years, percent, 2012	5.2%	6.3%
Persons under 18 years, percent, 2012	19.9%	23.1%
Persons 65 years and over, percent, 2012	18.5%	14.2%
Female persons, percent, 2012	51.1%	51.2%
White alone, percent, 2012 (a)	96.9%	79.3%
Black or African American alone, percent, 2012 (a)	1.4%	17.0%
American Indian and Alaska Native alone, percent, 2012 (a)	0.2%	0.4%
Asian alone, percent, 2012 (a)	0.3%	1.6%
Native Hawaiian and Other Pacific Islander alone, percent, 2012 (a)	Z	0.1%
Two or More Races, percent, 2012	1.1%	1.6%
Hispanic or Latino, percent, 2012 (b)	1.7%	4.8%
White alone, not Hispanic or Latino, percent, 2012	95.4%	75.1%
Living in same house 1 year & over, percent, 2007-2011	86.3%	84.1%
Foreign born persons, percent, 2007-2011	0.9%	4.5%
Language other than English spoken at home, percent age 5+, 2007-2011	1.8%	6.4%
High school graduate or higher, percent of persons age 25+, 2007-2011	78.6%	83.2%
Bachelor's degree or higher, percent of persons age 25+, 2007-2011	15.7%	23.0%
Veterans, 2007-2011	5,470	501,665
Mean travel time to work (minutes), workers age 16+, 2007-2011	22.0	24.0
Housing units, 2011	27,821	2,829,025
Homeownership rate, 2007-2011	72.9%	69.0%
Housing units in multi-unit structures, percent, 2007-2011	12.4%	18.1%
Median value of owner-occupied housing units, 2007-2011	\$96,900	\$137,200
Households, 2007-2011	24,190	2,457,997
Persons per household, 2007-2011	2.31	2.50
Per capita money income in the past 12 months (2011 dollars), 2007-2011	\$18,269	\$24,197
Median household income, 2007-2011	\$32,148	\$43,989
Persons below poverty level, percent, 2007-2011	22.0%	16.9%
Business QuickFacts	Carter County	Tennessee
Private nonfarm establishments, 2011	710	129,489 ¹
Private nonfarm employment, 2011	8,719	2,300,542 ¹
Private nonfarm employment, percent change, 2010-2011	-3.5%	1.6% ¹
Nonemployer establishments, 2011	3,366	473,451
Total number of firms, 2007	3,938	545,348
Black-owned firms, percent, 2007	S	8.4%
American Indian- and Alaska Native-owned firms, percent, 2007	F	0.5%
Asian-owned firms, percent, 2007	S	2.0%
Native Hawaiian and Other Pacific Islander-owned firms,		

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State & County QuickFacts

Unicoi County, Tennessee

People QuickFacts	Unicoi County	Tennessee
Population, 2012 estimate	18,235	6,456,243
Population, 2010 (April 1) estimates base	18,313	6,346,113
Population, percent change, April 1, 2010 to July 1, 2012	-0.4%	1.7%
Population, 2010	18,313	6,346,105
Persons under 5 years, percent, 2012	4.7%	6.3%
Persons under 18 years, percent, 2012	19.8%	23.1%
Persons 65 years and over, percent, 2012	20.6%	14.2%
Female persons, percent, 2012	51.0%	51.2%
White alone, percent, 2012 (a)	98.1%	79.3%
Black or African American alone, percent, 2012 (a)	0.4%	17.0%
American Indian and Alaska Native alone, percent, 2012 (a)	0.3%	0.4%
Asian alone, percent, 2012 (a)	0.2%	1.6%
Native Hawaiian and Other Pacific Islander alone, percent, 2012 (a)	Z	0.1%
Two or More Races, percent, 2012	1.0%	1.6%
Hispanic or Latino, percent, 2012 (b)	4.2%	4.8%
White alone, not Hispanic or Latino, percent, 2012	94.0%	75.1%
Living in same house 1 year & over, percent, 2007-2011	88.0%	84.1%
Foreign born persons, percent, 2007-2011	3.0%	4.5%
Language other than English spoken at home, percent age 5+, 2007-2011	5.2%	6.4%
High school graduate or higher, percent of persons age 25+, 2007-2011	75.3%	83.2%
Bachelor's degree or higher, percent of persons age 25+, 2007-2011	11.7%	23.0%
Veterans, 2007-2011	1,736	501,665
Mean travel time to work (minutes), workers age 16+, 2007-2011	24.7	24.0
Housing units, 2011	8,857	2,829,025
Homeownership rate, 2007-2011	72.9%	69.0%
Housing units in multi-unit structures, percent, 2007-2011	6.6%	18.1%
Median value of owner-occupied housing units, 2007-2011	\$115,200	\$137,200
Households, 2007-2011	7,437	2,457,997
Persons per household, 2007-2011	2.39	2.50
Per capita money income in the past 12 months (2011 dollars), 2007-2011	\$20,753	\$24,197
Median household income, 2007-2011	\$35,265	\$43,989
Persons below poverty level, percent, 2007-2011	20.7%	16.9%
Business QuickFacts	Unicoi County	Tennessee
Private nonfarm establishments, 2011	248	129,489 ¹
Private nonfarm employment, 2011	3,990	2,300,542 ¹
Private nonfarm employment, percent change, 2010-2011	-1.8%	1.6% ¹
Nonemployer establishments, 2011	786	473,451
Total number of firms, 2007	1,233	545,348
Black-owned firms, percent, 2007	F	8.4%
American Indian- and Alaska Native-owned firms, percent, 2007	F	0.5%
Asian-owned firms, percent, 2007	S	2.0%
Native Hawaiian and Other Pacific Islander-owned firms,		

Recent advances in cardiac PET and PET/CT myocardial perfusion imaging

Gary V. Heller, MD, PhD,^a Dennis Calnon, MD,^b and Sharmila Dorbala, MD^c

Cardiovascular imaging has gained an important role in the evaluation of patients with either known or suspected coronary artery disease. The choices have expanded, imaging procedures have improved. Currently, testing procedures include echocardiography, magnetic resonance imaging, cardiac CTA, cardiac catheterization, and nuclear myocardial perfusion imaging with either single photon emission computed tomography (SPECT) or positron emission tomography (PET). Each of these imaging modalities has its strengths and weaknesses. However, SPECT myocardial perfusion imaging has emerged as a reliable and widely available tool for physicians to use in the assessment of their patient for the exclusion or presence and severity of CAD. Recently, cardiac PET has emerged as an alternative to SPECT imaging.

Cardiac positron emission tomography (PET) imaging has gained considerable support and use in the field of cardiovascular imaging over the past several years. For example, delivery of the most accessible PET tracer, Rubidium-82 (RB-82) has quadrupled; the use of myocardial viability studies has increased, and the value of cardiac PET perfusion imaging is now being recognized. This recent increase in activity and interest has been spearheaded by several factors, such as availability of the camera technology, advances in cardiac PET acquisition and perfusion procedures, improved display procedures and software, as well as literature supporting the diagnostic and prognostic accuracy of PET perfusion

imaging. This review will highlight cardiac PET as presented in a recent symposium with regards to differences between SPECT imaging and PET, literature supporting cardiac PET for both diagnostic accuracy and risk stratification, and features of cardiac PET/CT that differentiate it from SPECT. The review includes recent literature advances.

SINGLE-PHOTON-COMPUTED TOMOGRAPHIC IMAGING: STRENGTHS AND WEAKNESSES

Single-photon-computed tomographic imaging (SPECT) has been successfully performed for over 30 years. Over 6 million studies are performed annually with a rich literature confirming both diagnostic and accuracy prognostic value. Over these years, considerable advancement has been made in the technology to improve image quality and shorten acquisition protocols. Its strengths are many including standardized protocols, ease of use, availability, and established guidelines (Table 1).

Despite these advances, however, several limitations of SPECT remain (Table 2). It is well recognized that SPECT techniques frequently underestimate the degree of ischemia and therefore the presence of multivessel coronary artery disease. The stress imaging protocols are inefficient and require much longer time than similar protocols for echo, CT, or even cardiac catheterization (2.5-4 vs 1 hour or less for other procedures). Recent advancements have targeted these long procedures including shortened acquisition times, as recently summarized by Slomka et al.¹ Attenuation artifact with SPECT imaging is commonplace despite efforts to identify using techniques such as prone imaging, attenuation correction, and/or ECG-gated SPECT imaging. Tracer activity in the liver and gut structures are common with SPECT imaging, particularly popular technetium-based imaging agents. As a result, interpretative confidence is sometimes lacking.

CARDIAC PET PERFUSION IMAGING AS AN ALTERNATIVE TO SPECT

An alternative to SPECT imaging is cardiac PET perfusion imaging. PET offers many advantages (Table 3). These advantages include higher spatial and contrast resolution, resulting in higher image quality and

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The review includes a summary of presentations made by the authors at a symposium sponsored by the same organization at the Annual Scientific Sessions of ASNC in San Diego, September 10-14, 2007 as well as recent advancements in the literature.

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Table 1. Strengths of SPECT myocardial perfusion imaging

Standardized protocols
Small, relatively inexpensive camera systems suitable for offices
Well documented literature for diagnostic accuracy
Well documented literature for risk stratification
ACC/ASNC guidelines, appropriateness criteria
Great acceptance by cardiology community

Table 2. Limitations of SPECT myocardial perfusion imaging

SPECT techniques underestimate ischemia severity
Imaging protocols are inefficient (commonly 2-4 hours)
Attenuation artifacts are common
GI tracer interference is common
Interpretation confidence is often lacking

Table 3. Advantages of cardiac PET and PET/CT

Improved image quality
Higher spatial and contrast resolution
Accurate attenuation correction
Higher diagnostic accuracy
Excellent risk stratification
Rapid procedure
Rest and peak stress gating
Added information: blood flow, calcium, coronary CT

improved diagnostic accuracy. Attenuation correction, a technique validated with SPECT but infrequently used, is performed on every PET perfusion study. Excellent data are emerging with regards to risk stratification with PET perfusion. With Rb-82 as the radiotracer, the procedure is rapid (30-40 minutes, in comparison to 2.5-4 hours). Finally, added information such as regional blood flow, calcium scoring, and coronary CT can be provided, depending on instrumentation.

ADVANTAGES OF PET PERFUSION IMAGING

Improved Image Quality

The higher energy level of PET radiopharmaceutical activity (511 vs 140 keV for technetium) provides markedly improved image quality due to higher spatial resolution, less scatter, and common use of attenuation correction. These factors improve image quality and

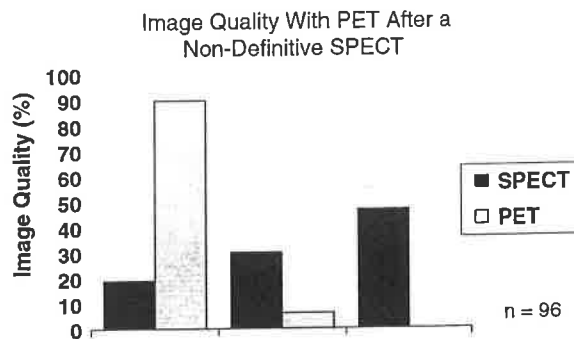


Figure 1. Comparison of image quality in patients undergoing SPECT and PET imaging. Adapted from Yoshinaga et al².

markedly reduce attenuation artifact. Image quality was recently studied by Yoshinaga et al² in which patients with equivocal SPECT studies were referred for cardiac PET imaging. In very high percentage of patients, the PET study patient resulted in good to excellent image quality, 90% for PET, 20% for SPECT (Figure 1). In that study, there was an obvious referral bias, but still demonstrated striking differences in quality in the same patient. Using a comparison of similar but matched patients undergoing SPECT or PET, Bateman, et al³ also reported a significant improvement in image quality with PET.

Attenuation artifact has been a major interpretation challenge for SPECT imaging. Because of the higher imaging activity of the radiopharmaceutical tracer as well as attenuation correction, PET imaging is far less susceptible to attenuation artifact. A recent study by Bateman et al³ evaluated artifact a similar group of SPECT and PET patients. As shown in Table 4 the incidence of significant artifact was reduced as well as gut uptake and particularly that in which interpretation could be compromised. A common reason for PET imaging inconclusive studies is that of an inconclusive

Table 4. Comparison of artifact between SPECT and PET perfusion imaging

	SPECT	PET	P value
No artifact	19 (17%)	49 (44%)	.0001
Minor artifact	26 (23%)	28 (25%)	.75
Significant artifact	64 (57%)	33 (29%)	.0003
Major artifact	3 (3%)	2 (2%)	.32
No GI uptake	45 (40%)	100 (89%)	<.001
Minor GI uptake	19 (17%)	5 (4%)	.0002
Significant GI uptake	46 (41%)	6 (5%)	<.001
Major GI uptake	2 (2%)	1 (1%)	.32

SPECT, Single photon emission computed tomography; PET, positron emission tomography; GI, gastrointestinal (Bateman et al³).

Diagnostic accuracy of rest/stress ECG-gated Rb-82 myocardial perfusion PET: Comparison with ECG-gated Tc-99m sestamibi SPECT

Timothy M. Bateman, MD,^{abc} Gary V. Heller, MD, PhD,^d A. Iain McGhie, MD,^{ac} John D. Friedman, MD,^e James A. Case, PhD,^{bc} Jan R. Bryngelson, BN,^b Ginger K. Hertenstein, CNMT,^b Kelly L. Moutray, MEd,^c Kimberly Reid, MS,^c and S. James Cullom, PhD^{bc}

Background. Although single photon emission computed tomography (SPECT) and positron emission tomography (PET) myocardial perfusion imaging (MPI) have evolved considerably over the last decade, there is no recent comparison of diagnostic performance. This study was designed to assess relative image quality, interpretive confidence, and diagnostic accuracy by use of contemporary technology and protocols.

Methods and Results. By consensus and without clinical information, 4 experienced nuclear cardiologists interpreted 112 SPECT technetium-99m sestamibi and 112 PET rubidium-82 MPI electrocardiography (ECG)-gated rest/pharmacologic stress studies in patient populations matched by gender, body mass index, and presence and extent of coronary disease. The patients were categorized as having a low likelihood for coronary artery disease (27 in each group) or had coronary angiography within 60 days. SPECT scans were acquired on a Cardio-60 system and PET scans on an ECAT ACCEL scanner. Image quality was excellent for 78% and 79% of rest and stress PET scans, respectively, versus 62% and 62% of respective SPECT scans (both $p < .05$). An equal percent of PET and SPECT gated images were rated excellent in quality. Interpretations were definitely normal or abnormal for 96% of PET scans versus 81% of SPECT scans ($p = .001$). Diagnostic accuracy was higher for PET for both stenosis severity thresholds of 70% (89% vs 79%, $p = .03$) and 50% (87% vs 71%, $p = .003$) and was higher in men and women, in obese and nonobese patients, and for correct identification of multivessel coronary artery disease.

Conclusion. In a large population of matched pharmacologic stress patients, myocardial perfusion PET was superior to SPECT in image quality, interpretive certainty, and diagnostic accuracy. (J Nucl Cardiol 2006;13:24-33.)

Key Words: Single photon emission computed tomography • positron emission tomography • myocardial perfusion imaging

See related article, p. 2

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Radionuclide myocardial perfusion imaging (MPI) is performed worldwide for assessing patients with known or suspected coronary artery disease (CAD). Most commonly, either thallium-201 or a technetium-99m perfusion tracer is used via single photon emission computed tomography (SPECT). An alternative is myocardial perfusion positron emission tomography (PET) using either cyclotron-produced ammonia or generator-produced rubidium 82.¹ There are several potential advantages of PET MPI, such as higher spatial resolution, greater counting efficiencies, and robust attenuation correction. All of these factors presumably form the basis of improved diagnostic accuracy in comparison to SPECT in studies performed more than a decade ago.²⁻⁶ Although these studies were instrumental in shaping

Impact of Myocardial Perfusion Imaging with PET and ^{82}Rb on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management

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We hypothesized that PET myocardial perfusion imaging with ^{82}Rb (PET MPI), would reduce downstream utilization of diagnostic arteriography, compared with SPECT, in patients matched for pretest likelihood of coronary disease (pCAD). PET MPI is more accurate for assessment of impaired coronary flow reserve compared with SPECT MPI, potentially reducing the demand for subsequent arteriography, percutaneous transcatheter intervention, and coronary artery bypass grafting (CABG), with attendant cost savings, while avoiding a negative impact on coronary events. **Methods:** The frequency of diagnostic arteriography, revascularization, costs, and 1-y clinical outcomes in 2,159 patients studied with PET MPI was compared with 2 control groups studied with SPECT MPI matched to the PET group by pCAD: an internal control group of 102 patients and an external SPECT control group of 5,826 patients. CAD management costs were approximated with realistic global fee estimates. **Results:** Arteriography rates were 0.34 and 0.31 for the external and internal control SPECT groups and 0.13 for the patients studied with PET ($P < 0.0001$). pCAD averaged 0.39 in patients studied with PET MPI, and in the external SPECT control group, and 0.37 in the internal SPECT controls. Revascularization rates were 0.13 and 0.11 for external and internal SPECT patients and 0.06 for the PET group ($P < 0.0001$; $P < 0.01$), with a cost savings of 30% noted for PET patients, with no significant difference in cardiac death or myocardial infarction at 1-y follow-up. **Conclusion:** PET MPI in patients with intermediate pCAD results in a >50% reduction in invasive coronary arteriography and CABG, a 30% cost savings, and excellent clinical outcomes at 1 y compared with SPECT.

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Compelling evidence has demonstrated that invasive procedures such as coronary arteriography, coronary artery bypass grafting (CABG), and percutaneous transcatheter intervention (PTCI) are overutilized in the United States, contributing to unnecessary health care expense without improved patient outcomes (1–6). Management of coronary disease (CAD) currently utilizes noninvasive diagnostic testing as a “gatekeeper,” which typically provokes invasive coronary arteriography when results are abnormal, to provide a definitive diagnosis of CAD. Thereafter, mechanical myocardial revascularization is usually performed on the basis of the coronary lumenogram, often without improved outcome—specifically in the hard endpoints of coronary death and myocardial infarction (MI)—despite great cost (7). Previous theoretic models have indicated that increased diagnostic accuracy of noninvasive testing, specifically myocardial perfusion imaging using PET (PET MPI), may reduce costs and improve outcomes when used in place of SPECT (SPECT MPI), in the routine management of CAD (8,9), however, documentation of this hypothesis in a prospective trial has not been previously reported.

This study tests the hypothesis that a noninvasive strategy for CAD management using MPI, free of attenuation artifacts with improved resolution and image contrast due to substantially higher counts provided by PET, lowers costs of CAD management, through reduction of unnecessary downstream invasive diagnostic and therapeutic procedures, compared with conventional management with standard exercise SPECT, because of the improvement in diagnostic accuracy provided by PET.

In this study, clinical outcomes, procedure utilization, and costs were evaluated in 2,159 sequential patients imaged with PET MPI and compared with 2 control groups of patients, matched for pretest likelihood of CAD (pCAD), who were imaged with SPECT MPI.

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**Incremental Prognostic Value of Gated Rb-82 Positron Emission Tomography
Myocardial Perfusion Imaging Over Clinical Variables and Rest LVEF**

Sharmila Dorbala, Rory Hachamovitch, Zelmira Curillova, Deepak Thomas, Divya
Vangala, Raymond Y. Kwong, and Marcelo F. Di Carli

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Incremental Prognostic Value of Gated Rb-82 Positron Emission Tomography Myocardial Perfusion Imaging Over Clinical Variables and Rest LVEF

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Deepak Thomas, MD,* Divya Vangala,* Raymond Y. Kwong, MD,† Marcelo F. Di Carli, MD*†
Boston, Massachusetts; and Los Angeles, California

OBJECTIVES This investigation sought to study the incremental value of gated rubidium (Rb)-82 positron emission tomography (PET) myocardial perfusion imaging (MPI) over clinical variables for predicting survival and future cardiac events.

BACKGROUND The prognostic value of Rb-82 PET-MPI and left ventricular ejection fraction (LVEF) reserve (stress minus rest LVEF) is not well defined.

METHODS 1,432 consecutive patients undergoing gated rest/vasodilator stress rubidium-82 PET were followed up for at least 1 year. Of these, rest and peak stress LVEF and LVEF reserve were available in 985 patients. Cardiac events (CE) including cardiac death or nonfatal myocardial infarction and all-cause death were assessed.

RESULTS Over a mean follow-up of 1.7 ± 0.7 years, 83 (5.8%) CE and 140 (9.7%) all-cause death were observed. There was an increase in risk for both end points with an increasing percentage of abnormal and ischemic myocardium. With normal, mild, moderate, or severely ischemic scans, the observed annualized rates of CE were 0.7%, 5.5%, 5%, and 11% and of all-cause death were 3.3%, 7.2%, 6.9%, and 12.5%, respectively. In 985 patients with peak stress gated data, the observed annualized rates of CE (2.1% vs. 5.3%, $p < 0.001$) and all-cause death (4.3% vs. 9.2%, $p < 0.001$) were higher in patients with an LVEF reserve $<0\%$ compared with those with an LVEF reserve $\geq 0\%$. On Cox proportional hazards analysis, after consideration of clinical, historical, and rest LVEF information, stress PET results and LVEF reserve yielded incremental prognostic value with respect to both CE and all-cause death.

CONCLUSIONS Vasodilator stress Rb-82 PET-MPI provides incremental prognostic value to historical/clinical variables and rest LVEF to predict survival free of CE and all-cause death. An increasing percentage of ischemia on PET-MPI is associated with an increase in the risk of CE and all-cause death. Left ventricular ejection fraction reserve provides significant independent and incremental value to Rb-82 MPI for predicting the risk of future adverse events. (J Am Coll Cardiol Img 2009;2:846–54)
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ercise, or dobutamine PET studies because of inherent differences in baseline patient risk and levels and duration of peak coronary flow achieved.

CONCLUSIONS

The percentage of ischemic myocardium on vasodilator stress Rb-82 PET-MPI is a powerful predictor of CE and survival in patients with known CAD or an intermediate to high pre-test likelihood of CAD. Rb-82 PET-MPI provides significant incremental value over the baseline clinical variables, rest LVEF and stress data. The addition of LVEF reserve provides significant independent and

incremental value to Rb-82 MPI for stratifying risk of future serious adverse events.

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Key Words: prognosis ■
imaging ■ tomography.

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A Conversation with . . . Kim Giordano, CNMT

Bracco's solution to the Mo-99 isotope crisis

MOLYBDENUM-99 (MO-99) IS THE PRECURSOR FOR TECHNETIUM-99M, a radioisotope used in 80 percent of diagnostic and nuclear medicine procedures. However, earlier this year, following an unexpected shutdown at the Canadian nuclear reactor that provides 50 percent of the Mo-99 supply in the U.S., the nuclear medicine industry has been dealt a massive blow in the form of possible shortages.

Only a handful of facilities around the world can generate quantities of Mo-99 that can be exported for commercial use – of those five reactors, three are in Europe, one is in Canada, and one is in South Africa. Since these medical isotopes cannot be stockpiled, disruptions at even one of those facilities can quickly affect the chain of supply to the entire industry, leaving today's health-care professionals grasping for solutions.

One company – Princeton, N.J.-based Bracco Diagnostics Inc. – believes it has developed a viable solution to ease the strain of impending Mo-99 shortages with CardioGen-82, the only generator-based, cardiac PET perfusion imaging agent approved by the FDA. **rt image** sits down with Kim Giordano, Bracco's vice president of corporate accounts and nuclear medicine, as well as a certified nuclear medicine technologist, to discuss what relief this product is expected to bring to the Mo-99 shortage.

Q **rt image:** How does PET Myocardial Perfusion Imaging (MPI) provide a long-term solution to the current Mo-99 crisis?

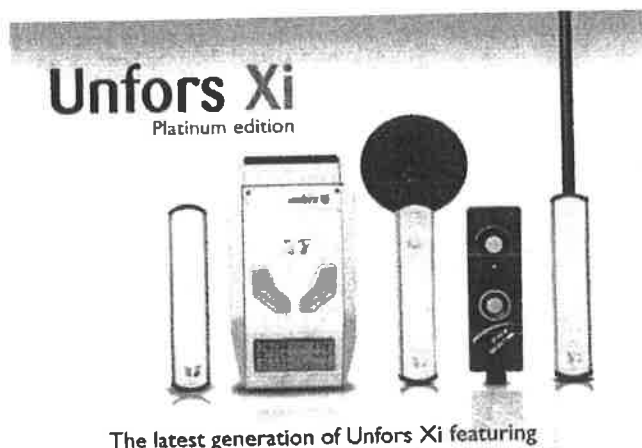
A **Kim Giordano:** Since CardioGen-82® (Rubidium Rb-82 Generator) is not reliant upon the supply of Mo-99, it has much greater availability for use in performing nuclear cardiology studies. Many centers that are experiencing difficulty obtaining the isotopes used for MPI with SPECT also have access to a PET scanner. Using PET instead of SPECT for MPI has many clinical and logistical advantages. Now cardiac PET with CardioGen-82 offers even more benefits because patient studies no longer have to be postponed or canceled due to the Mo-99 shortage. Facilities that offer PET MPI as part of their cardiac imaging service can continue to maintain and expand their nuclear cardiology patient volumes.

Q **image:** What advantages does PET offer over SPECT, clinically and logistically, for CAD patients and interpreting physicians?

A **Giordano:** PET images provide more than twice as many photon counts as SPECT images. This, combined with improved spatial resolution and attenuation correction on all scans, enhances the overall image quality and diagnostic accuracy. CardioGen-82 PET offers imagers greater interpretive certainty versus SPECT – 96 percent versus 82 percent respectively. Moreover, typical PET MPI protocols are completed (gated rest and stress) in 30 minutes to 45 minutes, instead of about three hours with SPECT. Therefore, PET provides both clinical and logistical advantages for CAD patients and interpreting physicians.

Q **image:** Are there any patients who would not benefit from a cardiac PET study, or are there contraindications to the test?

A **Giordano:** CardioGen-82 has no known contraindications. According to Medicare, PET is reimbursed for many of the



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Single-photon emission computed tomography

From Wikipedia, the free encyclopedia

Single-photon emission computed tomography (SPECT, or less commonly, SPET) is a nuclear medicine tomographic^[1] imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera. However, it is able to provide true 3D information. This information is typically presented as cross-sectional slices through the patient, but can be freely reformatted or manipulated as required.

The basic technique requires delivery of a gamma-emitting radioisotope (called radionuclide) into the patient, normally through injection into the bloodstream. On occasion, the radioisotope is a simple soluble dissolved ion, such as a radioisotope of gallium(III), which happens to also have chemical properties that allow it to be concentrated in ways of medical interest for disease detection. However, most of the time in SPECT, a marker radioisotope, which is of interest only for its radioactive properties, has been attached to a specific ligand to create a radioligand, which is of interest for its chemical binding properties to certain types of tissues. This marriage allows the combination of ligand and radioisotope (the radiopharmaceutical) to be carried and bound to a place of interest in the body, which then (due to the gamma-emission of the isotope) allows the ligand concentration to be seen by a gamma-camera.

Contents

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- 2 Application
 - 2.1 Myocardial perfusion imaging
 - 2.2 Functional brain imaging
- 3 Reconstruction
- 4 Typical SPECT acquisition protocols
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Principles

In the same way that a plain X-ray is a 2-dimensional (2-D) view of a 3-dimensional structure, the image obtained by a gamma camera is a 2-D view of 3-D distribution of a radionuclide.

SPECT imaging is performed by using a gamma camera to acquire multiple 2-D images (also called projections), from multiple angles. A computer is then used to apply a tomographic reconstruction algorithm to the multiple projections, yielding a 3-D dataset. This dataset may then be manipulated to show thin slices along any chosen axis of the body, similar to those obtained from other tomographic techniques, such as MRI, CT, and PET.

SPECT is similar to PET in its use of radioactive tracer material and detection of gamma rays. In contrast with PET, however, the tracer used in SPECT emits gamma radiation that is measured directly,

Single-photon emission computed tomography

Intervention



A SPECT slice of the distribution of technetium exametazime within a patient's brain.

ICD-9- 92.0 (<http://icd9cm.chrisendres.com/index.php?srctype=procs&srchtext=92.0&Submit=Search&action=search>)-92.1 (<http://icd9cm.chrisendres.com/index.php?srctype=procs&srchtext=92.1&Submit=Search&action=search>)

CM

MeSH D015899

OPS- 3-72 (<http://ops.icd-code.de/ops/code/3-72.html>)

301 code:



SPECT Siemens brand. It consists of

whereas PET tracer emits positrons that annihilate with electrons up to a few millimeters away, causing two gamma photons to be emitted in opposite directions. A PET scanner detects these emissions "coincident" in time, which provides more radiation event localization information and, thus, higher resolution images than SPECT (which has about 1 cm resolution). SPECT scans, however, are significantly less expensive than PET scans, in part because they are able to use longer-lived more easily-obtained radioisotopes than PET.

two gamma cameras.

Because SPECT acquisition is very similar to planar gamma camera imaging, the same radiopharmaceuticals may be used. If a patient is examined in another type of nuclear medicine scan but the images are non-diagnostic, it may be possible to proceed straight to SPECT by moving the patient to a SPECT instrument, or even by simply reconfiguring the camera for SPECT image acquisition while the patient remains on the table.



SPECT machine performing a total body bone scan. The patient lies on a table that slides through the machine, while a pair of gamma cameras rotate around her.

To acquire SPECT images, the gamma camera is rotated around the patient. Projections are acquired at defined points during the rotation, typically every 3–6 degrees. In most cases, a full 360-degree rotation is used to obtain an optimal reconstruction. The time taken to obtain each projection is also variable, but 15–20 seconds is typical. This gives a total scan time of 15–20 minutes.

Multi-headed gamma cameras can provide accelerated acquisition. For example, a dual-headed camera can be used with heads spaced 180 degrees apart, allowing 2 projections to be acquired simultaneously, with each head requiring 180 degrees of rotation. Triple-head cameras with 120-degree spacing are also used.

Cardiac gated acquisitions are possible with SPECT, just as with planar imaging techniques such as MUGA. Triggered by Electrocardiogram (EKG) to obtain differential information about the heart in various parts of its cycle, gated myocardial SPECT can be used to obtain quantitative information about myocardial perfusion, thickness, and contractility of the myocardium during various parts of the cardiac cycle, and also to allow calculation of left ventricular ejection fraction, stroke volume, and cardiac output.

Application

SPECT can be used to complement any gamma imaging study, where a true 3D representation can be helpful, e.g., tumor imaging, infection (leukocyte) imaging, thyroid imaging or bone scintigraphy.

Because SPECT permits accurate localisation in 3D space, it can be used to provide information about localised function in internal organs, such as functional cardiac or brain imaging.

Myocardial perfusion imaging

Main article: Myocardial perfusion imaging

Myocardial perfusion imaging (MPI) is a form of functional cardiac imaging, used for the diagnosis of ischemic heart disease. The underlying principle is that under conditions of stress, diseased myocardium receives less blood flow than normal myocardium. MPI is one of several types of cardiac stress test.

A cardiac specific radiopharmaceutical is administered, e.g., ^{99m}Tc-tetrofosmin (Myoview, GE healthcare), ^{99m}Tc-sestamibi (Cardiolite, Bristol-Myers Squibb). Following this, the heart rate is raised to induce myocardial stress, either by exercise or pharmacologically with adenosine, dobutamine, or dipyridamole (aminophylline can be used to reverse the effects of dipyridamole).

SPECT imaging performed after stress reveals the distribution of the radiopharmaceutical, and therefore the relative blood flow to the different regions of the myocardium. Diagnosis is made by comparing stress images to a further set of images obtained at rest. As the radionuclide redistributes slowly, it is not usually possible to perform both sets of images on the same day, hence a second attendance is required 1–7 days later (although, with a Tl-201 myocardial perfusion study with dipyridamole, rest images can be acquired as little as two hours post-stress). However, if stress imaging is normal, it is unnecessary to perform rest imaging, as it too will be normal; thus, stress imaging is normally performed first.

MPI has been demonstrated to have an overall accuracy of about 83% (sensitivity: 85%; specificity: 72%),^[2] and is comparable with (or better than) other non-invasive tests for ischemic heart disease.

Functional brain imaging

Main article: Neuroimaging

Usually, the gamma-emitting tracer used in functional brain imaging is ^{99m}Tc-HMPAO (hexamethylpropylene amine oxime). ^{99m}Tc is a metastable nuclear isomer that emits gamma rays that can be detected by a gamma camera. Attaching it to HMPAO allows ^{99m}Tc to be taken up by brain tissue in a manner proportional to brain blood flow, in turn allowing cerebral blood flow to be assessed with the nuclear gamma camera.

Because blood flow in the brain is tightly coupled to local brain metabolism and energy use, the ^{99m}Tc-HMPAO tracer (as well as the similar ^{99m}Tc-EC tracer) is used to assess brain metabolism regionally, in an attempt to diagnose and differentiate the different causal pathologies of dementia. Meta-analysis of many reported studies suggests that SPECT with this tracer is about 74% sensitive at diagnosing Alzheimer's disease vs. 81% sensitivity for clinical exam (cognitive testing, etc.). More recent studies have shown the accuracy of SPECT in Alzheimer's diagnosis may be as high as 88%.^[3] In meta analysis, SPECT was superior to clinical exam and clinical criteria (91% vs. 70%) in being able to differentiate Alzheimer's disease from vascular dementias.^[4] This latter ability relates to SPECT's imaging of local metabolism of the brain, in which the patchy loss of cortical metabolism seen in multiple strokes differs clearly from the more even or "smooth" loss of non-occipital cortical brain function typical of Alzheimer's disease.

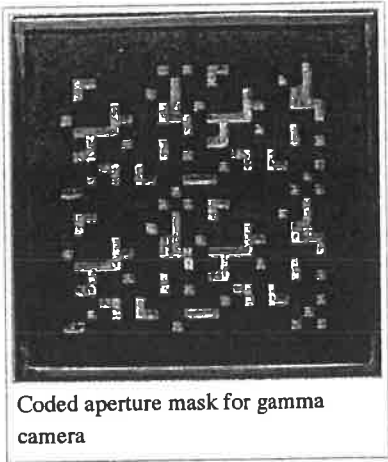
^{99m}Tc-HMPAO SPECT scanning competes with fludeoxyglucose (FDG) PET scanning of the brain, which works to assess regional brain glucose metabolism, to provide very similar information about local brain damage from many processes. SPECT is more widely available, because the radioisotope used is longer-lasting and far less expensive in SPECT, and the gamma scanning equipment is less expensive as well. While ^{99m}Tc is extracted from relatively simple technetium-99m generators, which are delivered to hospitals and scanning centers weekly to supply fresh radioisotope, FDG PET relies on FDG, which is made in an expensive medical cyclotron and "hot-lab" (automated chemistry lab for radiopharmaceutical manufacture), and then delivered immediately to scanning sites because of the natural short 110-minute half-life of Fluorine-18.

Reconstruction

Reconstructed images typically have resolutions of 64×64 or 128×128 pixels, with the pixel sizes ranging from 3–6 mm. The number of projections acquired is chosen to be approximately equal to the width of the resulting images. In general, the resulting reconstructed images will be of lower resolution, have increased noise than planar images, and be susceptible to artifacts.

Scanning is time consuming, and it is essential that there is no patient movement during the scan time. Movement can cause significant degradation of the reconstructed images, although movement compensation reconstruction techniques can help with this. A highly uneven distribution of radiopharmaceutical also has the potential to cause artifacts. A very intense area of activity (e.g., the bladder) can cause extensive streaking of the images and obscure neighboring areas of activity. (This is a limitation of the filtered back projection reconstruction algorithm. Iterative reconstruction is an alternative algorithm that is growing in importance, as it is less sensitive to artifacts and can also correct for attenuation and depth dependent blurring).

Attenuation of the gamma rays within the patient can lead to significant underestimation of activity in deep tissues, compared to superficial tissues. Approximate correction is possible, based on relative position of the activity. However, optimal correction is obtained with measured attenuation values. Modern SPECT equipment is available with an integrated X-ray CT scanner. As X-ray CT images are an attenuation map of the tissues, this data can be incorporated into the SPECT reconstruction to correct for attenuation. It also provides a precisely registered CT image, which can provide additional anatomical information.



Typical SPECT acquisition protocols

Study	Radioisotope	Emission energy (keV)	Half-life	Radiopharmaceutical	Activity (MBq)	Rotation (degrees)	Projections	Image resolution	Time per projection (s)
	technetium-		6	Phosphonates /					

Bone scan	99m	140	hours	Bisphosphonates	800	360	120	128 x 128	30
Myocardial perfusion scan	technetium-99m	140	6 hours	tetrofosmin; Sestamibi	700	180	60	64 x 64	25
Sestamibi parathyroid scan	technetium-99m	140	6 hours	Sestamibi					
Brain scan	technetium-99m	140	6 hours	HMPAO; ECD	555-1110	360	64	128 x 128	30
Neuroendocrine or neurological tumor scan	iodine-123 or iodine-131	159	13 hours or 8 days	MIBG	400	360	60	64 x 64	30
White cell scan	indium-111 & technetium-99m	171 & 245	67 hours	<i>in vitro</i> labelled leucocytes	18	360	60	64 x 64	30

SPECT/CT

In some cases a SPECT gamma scanner may be built to operate with a conventional CT scanner, with coregistration of images. As in PET/CT, this allows location of tumors or tissues which may be seen on SPECT scintigraphy, but are difficult to precisely locate with regard to other anatomical structures. Such scans are most useful for tissues outside the brain, where location of tissues may be far more variable. For example, SPECT/CT may be used in sestamibi parathyroid scan applications, where the technique is useful in locating ectopic parathyroid adenomas which may not be in their usual locations in the thyroid gland.^[5]

See also

- Gamma camera
- Neuroimaging
- Functional neuroimaging
- Magnetic resonance imaging
- Positron emission tomography
- ISAS (Ictal-Interictal SPECT Analysis by SPM)

References

- ↑ SPECT (http://www.nlm.nih.gov/cgi/mesh/2011/MB_cgi?mode=&term=SPECT) at the US National Library of Medicine Medical Subject Headings (MeSH)
- ↑ Elhendy, A; Bax, JJ; Poldermans, D (2002). "Dobutamine stress myocardial perfusion imaging in coronary artery disease.". *Journal of Nuclear Medicine* **43** (12): 1634–46. PMID 12468513 (<http://www.ncbi.nlm.nih.gov/pubmed/12468513>).
- ↑ Bonte FJ, Harris TS, Hynan LS, Bigio EH, White CL (2006). "Tc-99m HMPAO SPECT in the differential diagnosis of the dementias with histopathologic confirmation". *Clin Nucl Med* **31** (7): 376–8. doi:10.1097/01.rlu.0000222736.81365.63 (<http://dx.doi.org/10.1097%2F01.rlu.0000222736.81365.63>). PMID 16785801 (<http://www.ncbi.nlm.nih.gov/pubmed/16785801>).
- ↑ Dougall NJ, Bruggink S, Ebmeier KP (2004). "Systematic review of the diagnostic accuracy of 99mTc-HMPAO-SPECT in dementia". *Am J Geriatr Psychiatry* **12** (6): 554–70. doi:10.1176/appi.ajgp.12.6.554 (<http://dx.doi.org/10.1176%2Fappi.ajgp.12.6.554>). PMID 15545324 (<http://www.ncbi.nlm.nih.gov/pubmed/15545324>).
- ↑ [1] (<http://www.ncbi.nlm.nih.gov/pubmed/18997051>) PET/CT sestamibi vs. other modalities for parathyroid imaging

Further reading

- Herman, Gabor T. (2009). *Fundamentals of Computerized Tomography: Image Reconstruction from Projections* (2nd ed.). Springer. ISBN 978-1-85233-617-2..
- Elhendy *et al.*, Dobutamine Stress Myocardial Perfusion Imaging in Coronary Artery Disease, J Nucl Med 2002 43: 1634–1646 (<http://jnm.snmjournals.org/cgi/content/abstract/43/12/1634>)

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Find Shortage Areas: MUA/P by State and County

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Criteria:

State: Tennessee

County: ALL COUNTIES

ID #: All

Results: 324 records found.

Name	ID#	Type	Score	Designation Date	Update Date
Anderson County					
Anderson Service Area	03241	MUA	60.50	1984/07/24	1994/05/04
CT 0207.00					
CT 0208.00					
CT 0210.00					
CT 0212.01					
CT 0212.02					
Bedford County					
Bedford Service Area	03173	MUA	59.80	1978/11/01	
Benton County					
Benton Service Area	03174	MUA	56.70	1978/11/01	
Bledsoe County					
Bledsoe Service Area	03175	MUA	54.10	1978/11/01	
Blount County					
Blount Service Area	03262	MUA	58.84	1994/05/12	
CT 0101.00					
CT 0105.00					
CT 0112.00					
CT 0113.01					
CT 0113.02					
CT 0116.02					
Blount Service Area	03269	MUA	54.90	1994/05/12	
CT 0108.00					
Blount Service Area	03270	MUA	54.90	1994/07/12	
CT 0114.01					
CT 0114.02					
CT 9802.00					
Bradley County					
Cleveland Division Service Area	03253	MUA	43.20	1994/05/12	
MCD (90392) District 3					
MCD (90772) District 5					
MCD (90962) District 6					
MCD (91152) District 7					
Campbell County					
Campbell Service Area	03176	MUA	41.40	1978/11/01	
Cannon County					
Cannon Service Area	03177	MUA	55.40	1978/11/01	
Carroll County					
Carroll Service Area	03178	MUA	60.80	1978/11/01	
Carter County					
Carter Service Area	03179	MUA	55.20	1978/11/01	
Cheatham County					
Cheatham Service Area	03180	MUA	60.70	1978/11/01	
Chester County					
Chester Service Area	03181	MUA	48.80	1978/11/01	
Claiborne County					
Claiborne Service Area	03182	MUA	46.20	1978/11/01	
Clay County					
Clay Service Area	03183	MUA	37.60	1978/11/01	
Cocke County					
Cocke Service Area	03184	MUA	37.80	1978/11/01	
Coffee County					
Beech Grove Division Service Area	03254	MUA	42.30	1994/05/12	
MCD (90032) District 1					
MCD (91742) District 10					
MCD (91932) District 11					
MCD (92122) District 12					
MCD (92312) District 13					
MCD (90222) District 2					
MCD (90412) District 3					

CT 0220.23					
CT 0220.24					
CT 0221.11					
CT 0221.12					
CT 0222.10					
CT 0222.20					
CT 0223.10					
CT 0223.21					
CT 0223.30					
CT 0224.10					
CT 0225.00					
CT 0227.00					
Nw Memphis Service Area	07469	MUA	56.00	2005/04/06	
CT 0002.00					
CT 0003.00					
CT 0004.00					
CT 0006.00					
CT 0007.00					
CT 0008.00					
CT 0009.00					
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CT 0113.00					
CT 0205.21					
CT 0205.23					
CT 0205.24					
Smith County					
Forks Of The River Service Area	03267	MUA	60.80	1994/05/12	
MCD (91490) District 8					
Stewart County					
Stewart Service Area	03231	MUA	58.80	1978/11/01	
Sullivan County					
No MUAs in this county.					
Sumner County					
Sumner Service Area	03251	MUA	53.05	1994/07/12	
CT 0201.01					
CT 0201.02					
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CT 0202.06					
CT 0202.07					
CT 0202.08					
CT 0202.09					
CT 0203.00					
CT 0207.00					
CT 0208.00					
Tipton County					
Tipton Service Area	03232	MUA	44.90	1978/11/01	
Trousdale County					
Trousdale Service Area	03233	MUA	53.30	1978/11/01	
Unicoi County					
Unicoi County	03234	MUA	59.30	1978/11/01	2012/05/14
Union County					
Union Service Area	03235	MUA	43.50	1978/11/01	
Van Buren County					
Van Buren Service Area	03236	MUA	59.00	1978/11/01	
Warren County					
Warren Service Area	07036	MUA	57.40	1978/11/01	
Washington County					
Bethesda Division Service Area	03268	MUA	42.20	1994/05/12	
MCD (90940) District 5					
MCD (91510) District 8					
MCD (91700) District 9					
Wayne County					
Wayne Service Area	03237	MUA	47.90	1978/11/01	

SUPPORT LETTERS

**NOTIFICATION OF INTENT
TO APPLY FOR A CERTIFICATE OF NEED**

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Karing Hearts Cardiology, PLLC (a private professional medical practice), owned and managed by Jeffrey Schoondyke, M.D. (a physician), intends to file an application for a Certificate of Need to initiate Cardiac PET services and to acquire Cardiac PET equipment, at its practice office at 701 State of Franklin Road, Suite 2, Johnson City, TN 37604, at a capital cost estimated at \$500,000.

The project will not add or discontinue any other significant health service at this medical practice; and the project does not include any other type of major medical equipment.

The anticipated date of filing the application is on or before November 15, 2013. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

Olde Tyme Auction
318 Cumberland Street
Kingsport 423-392-0726
TFL-3823

Stewarts Hill Auction
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Jonesborough, TN 788-0275
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We provide flexible hours to accommodate your schedule. Must have reliable transportation and be able to work weekends. This position is a contracted position. Pay is performance based. Successful applicants must be able to begin immediately.

Applications will be accepted Monday through Friday from 8 am to 5 pm. The Johnson City Press is located at 204 W. Main St., Johnson City, or email your resume to snewcom@johnsoncitypress.com. No phone calls for this position are accepted.

The Johnson City Press is currently accepting applications for **part-time telemarketing sales clerk**. We have openings in our morning, afternoon and evenings shifts. Must have a pleasant phone voice. This is a contracted position. Pay is performance based. Successful applicants must be able to begin immediately.

Applications will be accepted Monday through Friday from 8 am to 5 pm. The Johnson City Press is located at 204 W. Main St., Johnson City, or email your resume to snewcom@johnsoncitypress.com. No phone calls for this position are accepted. Previous applicants need not apply.

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LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Johnson City Press, which is a newspaper of general circulation in Washington County, Tennessee, on or before November 10, 2013, for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Karing Hearts Cardiology, PLLC (a private professional medical practice), owned and managed by Jeffrey Schoondyke, M.D. (a physician), intends to file an application for a Certificate of Need to initiate Cardiac PET services and to acquire Cardiac PET equipment, at its practice office at 701 State of Franklin Road, Suite 2, Johnson City, TN 37604, at a capital cost estimated at \$500,000.

The project will not add or discontinue any other significant health service at this medical practice; and the project does not include any other type of major medical equipment.

The anticipated date of filing the application is on or before November 15, 2013. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

	11-8-13	jwdsg@comcast.net
(Signature)	(Date)	(E-mail Address)



State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364/Fax:615/532-9940

November 22, 2013

John Wellborn
Development Support Group
4219 Hillsboro Road, Suite #210
Nashville, Tennessee 37215

RE: Certificate of Need Application CN1311-046
Karing Hearts Cardiology, PLLC

Dear Mr. Wellborn:

This will acknowledge our November 13, 2013 receipt of your application for a Certificate of Need to initiate Cardiac PET services and to acquire Cardiac PET equipment, at its practice office at 701 State of Franklin Road, Suite 2, Johnson City (Washington County), TN.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Please submit responses in triplicate by 12:00 noon, Tuesday November 26, 2013. If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

1. Section A, Applicant Profile, Item 1

Please clarify the correct address of the applicant. The applicant states the address is 701 State of Franklin Road, but portions of the previously approved application, Molecular Imaging Alliance, CN1304-004 and the Architect's letter in this application, refer to the address as "North State of Franklin Road". Please clarify.

2. Section A, Applicant Profile, Item 3

Please clarify if Karing Hearts Cardiology, PLLC is 100% owned by Dr. Jeffrey Schoondyke, MD. If not, please list the owners and percentage of ownership.

3. Section B, Project Description, Item I

The applicant has requested consent calendar for this project. Please address the reason consent calendar is being requested as it relates to each of the following: 1) Need, 2) Economic Feasibility, and the 3) Orderly Development to Health Care.

It is noted the applicant states the ODC owner (approved in CN1304-014) is seeking to exit the ODC business and to terminate its lease of the PET unit it now operates, without implementing the ODC at the new location in Johnson City. However, please clarify the following:

- The PET equipment lease agreement is between Karing Hearts Cardiology, PLLC and Lifescan Leasing, LLC. Lifescan Leasing, LLC has four members: please list those members.
- According to the State of Tennessee, Secretary of State, the principal and registered agent address of Lifescan Leasing LLC appears to be the same address as the prior approved CON application, Lifescan Tennessee, LLC dba Molecular Imaging Alliance, CN1304-014A. Please clarify.
- Please provide documentation from the State of Tennessee, Secretary of State that Lifescan Leasing of Tennessee, LLC is an active entity.
- The web-site for Karing Hearts Cardiology located at <http://karingheartscardiology.com/staff.php> shows Rob Gregory as the Vice-President of Karing Hearts Cardiology, located at 701 N. State of Franklin Road, Suite2, Johnson City, TN. Please clarify if this is the owner of the previously approved CON application, Lifescan Tennessee, LLC dba Molecular Imaging Alliance, CN1304-014A.
- Please clarify if the Robert Gregory has any ownership interest in Lifescan Leasing, LLC or Karing Hearts Cardiology, PLLC.
- The PET equipment appears to be owned by Karing Hearts Cardiology, PLLC (owned by Dr. Jeffrey Schoondyke) and leased to Lifescan Leasing, LLC (which Dr. Jeffrey Schoondyke is a member). Please clarify if there are any legal implications of possibly owning and referring patients to the PET equipment as being the lessee and owner.
- Please clarify if Lifescan Leasing of Tennessee, LLC has always maintained ownership of the proposed PET unit since it was in service at Molecular Imaging Alliance located in Gray, TN.
- Please clarify if Dr. Jeffrey Schoondyke has ownership in LifeScan Tennessee, LLC.

- It is noted Precision Nuclear, LLC will provide the applicant with radiopharmaceuticals. However, please clarify the address of Precision Nuclear, LLC. Please clarify if Dr. Jeffrey Schoondyke or Robert Gregory are members of the LLC or has ownership interests.

Please clarify if Karing Hearts will maintain possession of Suite 1 on the ground floor of the "701" Building" at the 701 North State of Franklin Road, Johnson, City, TN. Please explain how Suite 1 will be utilized by the applicant.

Why was it profitable to file this CON verses acquiring the existing approved CON (CN1304-014A).

4. Section B, Project Description, Item II.A.

The applicant states the medical practice will seek to maintain the accreditation by the Intersocietal Accreditation Commission (IAC). In terms of the IAC accreditation, please answer the following:

- Please indicate the current accreditation period and when it will be renewed.
- Please indicate the accreditation fee and if the fee was accounted on the Projected Data Chart.
- What areas is the applicant certified in by the IAC

5. Section B, Item II. E.

What is the age of the PET scanner?

6. Section C, Need, Item 1.a. (Service Specific Criteria (Specific Criteria, Positron Emission Tomography) Item 6.a.-6f

Please provide documentation that the proposed PET unit is FDA-certified for clinical use.

The applicant refers to "attachments" for questions 6.a-6f. Please specify where the attachments are located in the application and submit a replacement page.

7. Section C, Need, Item 1.a. (Service Specific Criteria (Specific Criteria, Positron Emission Tomography) Item 8a.

The applicant refers the reader to "attachments" in the application that documents underserved areas in the primary service area. Please provide a narrative response specific to this application and proposed service area.

8. Section C, Need, Item 6

Does the projected PET volume consider that instead of being an ODC open to all comers versus now being limited to two (2) cardiologists at Karing Hearts?

8. Section C. Economic Feasibility Item 1 (Project Cost Chart)

The letter from the Architect is noted. However, the address of the applicant in the letter is noted as N. State of Franklin Road. Please clarify.

9. Section C, Economic Feasibility, Item 4

Please provide a Historical Data Chart for Karing Hearts.

10. Section C, Economic Feasibility, Item 6B.

Table Ten is noted. However, it appears the average gross and net revenue charges in 2012 for Molecular Imaging Alliance, Gray is identical. Please clarify.

11. Section C, Economic Feasibility, Item 9.

The TennCare/Medicaid Gross Revenue of \$123,830 or 6% in Year One is noted. However, please clarify if that includes revenue from Virginia Medicaid.

Please indicate the gross revenue the applicant expects from Virginia Medicaid patients.

12. Articles

The applicant has provided a 4-page Article titled "*Single-photo Emission Computed Tomography*" from Wikipedia. Please clarify if Wikipedia is a reliable source for information regarding medical equipment.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." **For this application, the sixtieth (60th) day after written notification is January 20, 2014. If this application is not deemed complete by this date, the application will be deemed void.** Agency Rule 0720-10-.03(4)(d)(2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Resubmittal of the application must be accomplished in accordance with

Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the next review cycle, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Mr. John Wellborn
November 22, 2013
Page 6

Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely,

A handwritten signature in blue ink, appearing to read "Phillip M. Earhart", with a stylized flourish at the end.

Phillip M. Earhart
Health Services Development Examiner

PME

Enclosure

ORIGINAL- SUPPLEMENTAL-1

Karing Hearts Cardiology, PLLC

CN1311-046

November 25, 2013

Phillip M. Earhart, Health Planner III
Tennessee Health Services and Development Agency
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37203

RE: CON Application #1311-046
Karing Hearts Cardiology, PLLC

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. Section A, Applicant Profile, Item 1

Please clarify the correct address of the applicant. The applicant states the address is 701 State of Franklin Road, but portions of the previously approved application, Molecular Imaging Alliance, CN1304-004 and the Architect's letter in this application, refer to the address as "North State of Franklin Road". Please clarify.

They are interchangeable for practical purposes. There is only one State of Franklin Road in Johnson City, and only one "701" State of Franklin Road address. That road changes direction as it crosses US Highway 321 (Market Street) west of downtown. It is called "North" on the north side of US 321, "West" on the south side of US 321 until it reaches I-26, and "East" as it proceeds west past I-26. Karing Hearts Cardiology is in the only building on State of Franklin Road with a "701" address; this can be verified by phoning Trinity Taxi Company in Johnson City, telephone 423-232-88911. Karing Hearts' building is locally referred to simply as "the 701 Building"; and it receives mail addressed to "State of Franklin Road" as well as to "North State of Franklin Road."

All the notifications of intent published and submitted in prior approved CN1304-004, and in this current application CN1311-046, omitted the word "North" from the project address. Service area residents know the location of the project. Persons who Google the 701 number with any of the three alternative street names will be directed to Karing Hearts Cardiology. The local postal delivery service delivers Karing Hearts' mail whether addressed to 701, 701 North, 701 West, or 701 East, State of Franklin Road.

Attached following this page is corrected page 5R to bring the Executive Summary into conformity with the notifications of intent in both applications.

SECTION B: PROJECT DESCRIPTION

B.I. PROVIDE A BRIEF EXECUTIVE SUMMARY OF THE PROJECT NOT TO EXCEED TWO PAGES. TOPICS TO BE INCLUDED IN THE EXECUTIVE SUMMARY ARE A BRIEF DESCRIPTION OF PROPOSED SERVICES AND EQUIPMENT, OWNERSHIP STRUCTURE, SERVICE AREA, NEED, EXISTING RESOURCES, PROJECT COST, FUNDING, FINANCIAL FEASIBILITY AND STAFFING.

Proposed Services and Equipment

- LifeScan Tennessee, LLC, dba Molecular Imaging Alliance, owns and operates a licensed Outpatient Diagnostic Center ("ODC") in Gray, Tennessee, in northwest Washington County. It provides cardiac PET services. It is the only cardiac PET facility in Upper East Tennessee. In July 2013, it was unanimously granted CN1304-014 to relocate with one leased Cardiac PET unit to a smaller office space 10 miles east, at 701 State of Franklin Road, Johnson City, TN. This location adjoins the physician practice of Karing Hearts Cardiology, which has always been the largest referral source for this Cardiac PET ODC. Implementation of that relocation is suspended, pending HSDA decision on this application.
- The ODC's owner, Mr. Robert Gregory, is seeking to exit the ODC business and to terminate its lease of the PET unit it now operates, without implementing the ODC at the new location in Johnson City. The physicians of Karing Hearts Cardiology seek to lease that same PET unit to offer it as a service of their practice, so that the approved relocation of the service from Gray to Johnson City may be implemented. They do not want to acquire and operate the ODC that holds the CON (which could be done without further CON approval). If Karing Hearts Cardiology is approved to offer this service and implements that approval, then Molecular Imaging Alliance will turn in CN1304-014 to be voided.
- The project will serve counties already approved for this type of service. It will not change the scope of services, or the costs already approved for this service. This will be the third CON review for the Cardiac PET service, so consent calendar review is respectfully requested.
- The cardiac PET service will be housed in medical practice space, and will utilize practice staff consisting of a nuclear medicine tech, an RN (half time) and a receptionist (half time).

Ownership Structure

- The CON applicant is Karing Hearts Cardiology, PLLC, a Johnson City cardiology practice owned by Dr. Jeffrey Schoondyke, M.D. A second cardiologist, Dr. Melanie Davidson, joined the practice in late 2013. She is also an established cardiologist in the service area.

Service Area

- The Cardiac PET ODC was granted CON approval in CY2007, to provide cardiac PET services to all of Upper East Tennessee. It has been doing that for more than five years.

Page Two
November 25, 2013

2. Section A, Applicant Profile, Item 3

Please clarify if Karing Hearts Cardiology, PLLC is 100% owned by Dr. Jeffrey Schoondyke, MD. If not, please list the owners and percentage of ownership.

It is wholly owned by Jeffrey Schoondyke, MD. As stated on page 7 of the application, he is the sole member (i.e., owner) of the PLLC. There are no current plans for his employed colleague, Dr. Davidson, to become an owner.

3. Section B, Project Description, Item I

The applicant has requested consent calendar for this project. Please address the reason consent calendar is being requested as it relates to each of the following: 1) Need, 2) Economic Feasibility, and the 3) Orderly Development to Health Care.

Need: The project is needed to assure patient access to a cardiac PET imaging service that is clinically important, and which has been available to this area for years. The service was recently granted CON approval to relocate to this site, under an owner who now does not wish to go forward with owning the service, if the cardiology practice which is its principal user is able to use the equipment as a practice-based modality.

Economic Feasibility: The service currently operates with a positive margin, as an Outpatient Diagnostic Center. It is reliably projected to continue to operate feasibly at the new location, as a practice-based modality. Continuing increases in utilization at the new location are probable, based on this practice's recent addition of an established cardiologist, and on the cardiac PET ODC's utilization increases since opening five years ago. Increased utilization will strengthen its economic feasibility. Project financing is available.

Orderly Development: The project replaces a CON granted less than a year ago, for this same equipment, at this same location, to be utilized primarily by the same referring cardiology practice. The project is unopposed.

Page Three
November 25, 2013

It is noted the applicant states the ODC owner (approved in CN1304-014) is seeking to exit the ODC business and to terminate its lease of the PET unit it now operates, without implementing the ODC at the new location in Johnson City. However, please clarify the following:

General Response: An overall description of the relationship of parties to this project may be helpful, in addition to the specific responses below.

A cardiac PET service was originally granted CN00701-010, in the form of an ODC in the town of Gray, in Washington County, in 2007. The ODC, Lifescan of Tennessee, LLC, was wholly owned by Soteria Imaging, a national imaging company.

In 2012, Soteria decided to exit this service and dispose of its holdings. Its largest referral source for cardiac PET at that time was Karing Hearts Cardiology (Dr. Jeffrey Schoondyke) in Johnson City. Karing Hearts' Vice President, Robert Gregory, agreed to purchase 100% of the ODC; and Dr. Schoondyke organized a group to purchase Soteria's 60% controlling interest in the leasing company that Soteria set up to own and lease PET equipment to its ODC. Today, Robert Gregory is still the sole owner of the ODC that offers the service at the Molecular Imaging ODC; and the same four individuals listed elsewhere in these responses are still the only owners of the equipment leasing company.

In 2013, it became apparent that only one cardiac PET unit was needed in Washington County, so the equipment leasing company arranged to sell the second PET unit to Wellmont Cardiology, which was awarded a CON to acquire that unit and move it to its practice office in Kingsport, in Sullivan County.

Mr. Gregory simultaneously received CON approval (C1304-004) to relocate his ODC with the one remaining cardiac PET unit to leased space adjoining Karing Hearts Cardiology in Johnson City. However, upon more closely identifying the capital costs of creating and maintaining a licensed ODC there, Mr. Gregory would prefer to let the medical practice take over the equipment lease and make cardiac PET simply a service of the practice. It would be less expensive to develop and to operate. Hence this current CON application.

Page Four
November 25, 2013

a. The PET equipment lease agreement is between Karing Hearts Cardiology, PLLC and Lifescan Leasing, LLC. Lifescan Leasing, LLC has four members: please list those members.

In 2010, Soteria Imaging, the owner of Lifescan Tennessee, LLC dba Molecular Imaging Associates), formed an equipment leasing company to own and lease the PET units being used at Gray. That entity was Lifescan Leasing of Tennessee, LLC. It is not a party to this CON application. However, the following information is offered:

1. In December 2012, Soteria decided to sell its interest in the ODC and the leasing company. At that time, Lifescan Leasing was owned 60% by Soteria Imaging, and 40% by a separate LLC named "Positron Emission Technology Group, LLC" (or "PET-G"). PET-G was owned in 25% equal shares by Rob Gregory, Dr. Jeffrey Schoondyke, Dr. Bruce Boggs, and Julie Bentley, NP.

2. In December 2012, the four owners of PET-G purchased Soteria's 60% controlling interest in the leasing company, dividing *that 60% share* as follows: Dr. Boggs, Dr. Schoondyke, and Ms. Bentley acquired approximately 27.8% (rounded) and Robert Gregory acquired 16.7% (rounded). At the same time, Robert Gregory acquired ownership of the ODC itself. During 2013, the PET-G entity was dissolved and the same four owners acquired membership interests in the leasing company of approximately 28% each, except for Robert Gregory, who acquired approximately 16%.

3. In summary, today the ownership interests of the ODC and the equipment leasing company are as follows:

Lifescan Tennessee, LLC (the ODC): 100% of the membership interests are owned by Robert Gregory.

Lifescan Leasing of Tennessee, LLC (the equipment leasing company that owns the PET equipment and leases it to the ODC):

<u>Owner</u>	<u>Ownership Interest (Rounded)</u>
Julie Bentley, Nurse Practitioner	28%
Jeffrey Schoondyke, M.D. (Cardiologist)	28%
Bruce Boggs, M.D. (Primary Care)	28%
Robert Gregory (Practice VP and Mgr)	16%
	100%

Page Five
November 25, 2013

b. According to the State of Tennessee, Secretary of State, the principal and registered agent address of Lifescan Leasing LLC appears to be the same address as the prior approved CON application, Lifescan Tennessee, LLC dba Molecular Imaging Alliance, CN1304-014A. Please clarify.

LifeScan Leasing of Tennessee, LLC exists only to lease cardiac PET equipment to Lifescan Tennessee, LLC dba Molecular Imaging ODC. Mr. Gregory manages the business affairs of both entities. It is convenient for all correspondence to come to the same address.

c. Please provide documentation from the State of Tennessee, Secretary of State that Lifescan Leasing of Tennessee, LLC is an active entity.

It is active. Attached following this page is the documentation.

d. The web-site for Karing Hearts Cardiology located at <http://karingheartscardiology.com/staff.php> shows Rob Gregory as the Vice-President of Karing Hearts Cardiology, located at 701 N. State of Franklin Road, Suite2, Johnson City, TN. Please clarify if this is the owner of the previously approved CON application, Lifescan Tennessee, LLC dba Molecular Imaging Alliance, CN1304-014A.

Yes; Mr. Gregory is Vice President of Karing Hearts (he manages the practice), and he also owns 100% of the membership interests of LifeScan Tennessee, LLC dba Molecular Imaging Alliance, which holds CN1304-014A to move as a cardiac PET ODC from Gray to Johnson City.

e. Please clarify if Robert Gregory has any ownership interest in Lifescan Leasing, LLC or Karing Hearts Cardiology, PLLC.

Mr. Gregory owns no part of the PLLC. The PLLC, as stated in the application, has only one member (owner), who is Dr. Jeffrey Schoondyke. Mr. Gregory owns the interests in Lifescan Leasing, LLC that are shown in the above response to question 3a. His interests are minority interests.

f. The PET equipment appears to be owned by Karing Hearts Cardiology, PLLC (owned by Dr. Jeffrey Schoondyke) and leased to Lifescan Leasing, LLC (which Dr. Jeffrey Schoondyke is a member). Please clarify if there are any legal implications of possibly owning and referring patients to the PET equipment as being the lessee and owner.



Filing Information

Name: **Lifescan Leasing of Tennessee, LLC**

General Information

SOS Control # :	723955	Formation Locale:	DELAWARE
Filing Type:	Limited Liability Company - Foreign	Date Formed:	12/23/2010
Filing Date:	06/27/2013 10:21 AM	Fiscal Year Close	12
Status:	Active	Member Count:	4
Duration Term:	Perpetual		
Managed By:	Member Managed		

Registered Agent Address

CORPORATION SERVICE COMPANY
2908 POSTON AVE
NASHVILLE, TN 37203-1312

Principal Address

STE 2
830 SUNCREST DR
GRAY, TN 37615-3476

The following document(s) was/were filed in this office on the date(s) indicated below:

Date Filed	Filing Description	Image #
06/27/2013	Initial Filing	7217-1205

Active Assumed Names (if any)	Date	Expires
-------------------------------	------	---------

SUPPLEMENTAL- # 1**November 26, 2013**Department Home | Contact Us | Search: **12:40pm**

Administrative Hearings | Business Services | Charitable Fundraising | Elections | Library & Archives | Publications



Tennessee Secretary of State

Tre Hargett

Home Corporations Motor Vehicle Temp Liens Summons Trademarks UCC Workers' Comp Exemption More Services

Business Services Online > Search Business Information

Business Information Search

As of November 22, 2013 at 4:30 p.m. we have processed all corporate filings received in our office through November 22, 2013 and all annual reports received in our office through November 22, 2013.

Search: 1-1 of 1

Search Name: ☒ Starts With ☐ Contains

Control #:

Active Entities Only: ☐ Search

Control #	Entity Type	Name	Name Type	Name Status	Entity Filing Date	Entity Status
<u>000723955</u>	LLC	Lifescan Leasing of Tennessee, LLC DELAWARE	Entity	Active	06/27/2013	Active

1-1 of 1

Information about individual business entities can be queried, viewed and printed using this search tool for free.

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Division of Business Services
312 Rosa L. Parks Avenue, Snodgrass Tower, 6th Floor
Nashville, TN 37243
615-741-2286

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Page Six
November 25, 2013

No, Dr. Schoondyke does not own the PET equipment. It is owned by LifeScan Leasing of Tennessee, LLC, in which Dr. Schoondyke owns a minority membership interest, along with three other minority owners who are not related persons.

Dr. Schoondyke was advised by legal counsel that these relationships raise no issues of self-referral. He is a minority owner of a leasing company that receives a flat (unchanging) lease payment that does not vary either with (a) the referrals from Dr. Schoondyke's medical practice, or with (b) the total utilization of the leased equipment. The proposed equipment lease attached in the current application also specifies a flat lease rate that does not vary with any physician's referral volume and does not vary with the utilization of the equipment.

g. Please clarify if Lifescan Leasing of Tennessee, LLC has always maintained ownership of the proposed PET unit since it was in service at Molecular Imaging Alliance located in Gray, TN.

Soteria formed LifeScan Leasing of Tennessee, LLC on December 23, 2010. Before then, the PET equipment at Gray was owned by Soteria or by some Soteria subsidiary, such as Lifescan of Tennessee (the ODC)--the applicant does not know which.

h. Please clarify if Dr. Jeffrey Schoondyke has ownership in LifeScan Tennessee, LLC.

No; he does not have, and has never had, any ownership in Lifescan Tennessee, LLC.

i. It is noted Precision Nuclear, LLC will provide the applicant with radiopharmaceuticals. However, please clarify the address of Precision Nuclear, LLC. Please clarify if Dr. Jeffrey Schoondyke or Robert Gregory are members of the LLC or has ownership interests.

Precision Nuclear, LLC is located at 830 Suncrest Drive, Gray, TN 37615. Neither Dr. Schoondyke nor Robert Gregory has any ownership/membership interest in Precision Nuclear, LLC.

Page Seven
November 25, 2013

j. Please clarify if Karing Hearts will maintain possession of Suite 1 on the ground floor of the "701" Building at the 701 North State of Franklin Road, Johnson, City, TN. Please explain how Suite 1 will be utilized by the applicant.

Karing Hearts Cardiology leases Suites 1, 2, and 3 currently. They are all integrated into a single practice office. Suite 1, which once was to be leased to Molecular Imaging, no longer exists as a separate space. The area formerly known as Suite 1 has now been partially built out by the practice, for SPECT stress test imaging, which is a modality of nuclear medicine. It already contains a hot lab, patient prep room, etc. as shown on the floor plans in the application. That area also has unfinished space available for a cardiac PET room and control room. Karing Hearts uses "Suite 2" as the address for its entire 3-suite office, to distinguish the practice from Suites 4 et seq. that are leased to other tenants.

k. Why was it profitable to file this CON verses acquiring the existing approved CON (CN1304-014A).

The lease, renovation costs, and operating expenses for this diagnostic modality will be lower as a practice-based service, than if it were developed as a licensed Outpatient Diagnostic Center. Compared to the outstanding ODC CN1304-004, there will be less space attributable to the service (and no lease at all), lower renovation costs (only needed in part of former Suite 1), and lower operating expenses (no licensing fees; sharing space and staff with the practice).

4. Section B, Project Description, Item II.A.

The applicant states the medical practice will seek to maintain the accreditation by the Intersocietal Accreditation Commission (IAC). In terms of the IAC accreditation, please answer the following:

a. Please indicate the current accreditation period and when it will be renewed.

Lifescan Tennessee, LLC is currently accredited through August 31, 2015.

b. Please indicate the accreditation fee and if the fee was accounted on the Projected Data Chart.

For nuclear cardiology testing, IAC accreditation fees currently total \$3,300. Those were not included in the Projected Data Chart for CY2015. Attached following this page are revised Pages 45R (PDC) and 46R (notes) reflecting that additional expense for CY2015, even though if the project is completed before CY2015, that will be a CY2014 expense (which will not be an annual expense).

PROJECTED DATA CHART-- KARING HEARTS CARDIOLOGY CARDIAC PET SERVICE

SUPPLEMENTAL- # 1

November 26, 2013

12:40pm

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2015	CY 2016
	PATIENTS	678	745
	PROCEDURES	678	745
A.	Utilization Data		
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$	\$
2.	Outpatient Services	2,063,832	2,155,285
3.	Emergency Services		
4.	Other Operating Revenue (Specify) <u>See notes page</u>		
	Gross Operating Revenue	\$ 2,063,832	\$ 2,155,285
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ 866,809	\$ 905,220
2.	Provision for Charity Care (3%)	61,915	64,659
3.	Provisions for Bad Debt (1%)	20,638	21,553
	Total Deductions	\$ 949,363	\$ 991,431
	NET OPERATING REVENUE	\$ 1,114,469	\$ 1,163,854
D.	Operating Expenses		
1.	Salaries and Wages	\$ 107,500	\$ 110,725
2.	Physicians Salaries and Wages	225,000	231,750
3.	Supplies	425,106	467,115
4.	Taxes	3,343	3,492
5.	Depreciation	6,667	6,667
6.	Rent	10,860	10,860
7.	Interest, other than Capital	0	0
8.	Management Fees		
a.	Fees to Affiliates	0	0
b.	Fees to Non-Affiliates	0	0
9.	Other Expenses (Specify) <u>See notes page</u>	269,583	275,655
	<small>Dues, Utilities, Insurance, and Prop Taxes.</small>		
	Total Operating Expenses	\$ 1,048,059	\$ 1,106,263
E.	Other Revenue (Expenses) -- Net (Specify)	\$	\$
	NET OPERATING INCOME (LOSS)	\$ 66,410	\$ 57,591
F.	Capital Expenditures		
1.	Retirement of Principal	\$ 11,685	\$ 12,245
2.	Interest	5,857	5,297
	Total Capital Expenditures	\$ 17,542	\$ 17,542
	NET OPERATING INCOME (LOSS)		
	LESS CAPITAL EXPENDITURES	\$ 48,868	\$ 40,049

SUPPLEMENTAL- # 1

November 26, 2013

12:40pm

PROJECTED DATA CHART NOTES TO OTHER EXPENSES (LINE D9)

		CY2014	CY2015
Employee benefits		10,750	11,073
Overhead salaries		35,816	36,890
General office supplies		3,348	3,438
Advertising Bus dev		2,500	2,500
Meals and Entertainment		1,755	1,808
Utilities		16,054	16,535
Accreditation Fee		3,300	0
Service repairs		18,400	24,400
Insurance and Lice		2,495	2,569
Equip Lease		144,000	144,000
Billing fee	2.5%	27,862	29,096
Accounting		1,303	1,346
		2,000	2,000
	TOTAL	269,583	275,655

Overhead Salaries
mngmnt 25000
Med records 4992
Admin coord 5824

Supples (D3) Summary

	678	745
N-13 = \$380	\$257,640	\$283,100
Lexi = \$232	\$157,296	\$172,840
General = \$15	\$10,170	\$11,175
	\$425,106	\$467,115

Page Eight
November 25, 2013

c. What areas is the applicant certified in by the IAC?

Karing Hearts Cardiology is IAC certified in Echocardiography. A copy of its certification is attached after this page.

5. Section B, Item II. E.

What is the age of the PET scanner?

As stated on page 19 of the application, it was manufactured in 2002, and used by Soteria Imaging at another location until it was moved to the ODC in Gray. That would make it 11 years old.

6. Section C, Need, Item 1.a. (Service Specific Criteria (Specific Criteria, Positron Emission Tomography) Item 6.a.-6f

a. Please provide documentation that the proposed PET unit is FDA-certified for clinical use.

This letter is attached following the IAC document after this page.

b. The applicant refers to "attachments" for questions 6.a-6f. Please specify where the attachments are located in the application and submit a replacement page.

Please see revised pages 25R and 26 R, following this page. Also provided is a revised page 62R listing Attachment B.II.E.1 as the location for the FDA approval letter that will soon be submitted.

7. Section C, Need, Item 1.a. (Service Specific Criteria (Specific Criteria, Positron Emission Tomography) Item 8a.

The applicant refers the reader to "attachments" in the application that documents underserved areas in the primary service area. Please provide a narrative response specific to this application and proposed service area.

Attached is a revised page 27R adding that information.

Page Nine

CERTIFICATE OF ACCREDITATION

INTERSOCIETAL ACCREDITATION COMMISSION
ECHOCARDIOGRAPHY | ICAEL

hereby recognizes

KARING HEARTS CARDIOLOGY, PLLC

701 NORTH STATE OF FRANKLIN ROAD

SUITE 2

JOHNSON CITY, TENNESSEE

as an
ACCREDITED FACILITY
in the area(s) of
ADULT TRANSTHORACIC




PRESIDENT, ECHOCARDIOGRAPHY | ICAEL


SECRETARY, ECHOCARDIOGRAPHY | ICAEL

through the date of **NOVEMBER 30, 2015**

DEC 22 2000

K003849
SUPPLEMENTAL- # 1

November 26, 2013

12:40pm

Special 510(k) Premarket Notification
GE Medical Systems - GE Advance NXi Positron Emission Tomography System
December 11, 2000

Attachment B:

*Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).*



GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: D. Duersteler
Safety and Regulatory Engineering
Telephone: 262-785-8219; Fax: 262-785-8250

Date Prepared: December 11, 2000

Device Name: GE Advance NXi Positron Emission Tomography System.
Emission Computed Tomography System, 21 CFR 892.1200, 90-KPS

Marketed Device: GE Medical Systems GE Advance Positron Emission Tomography System, 510(k)
Numbers K923309, K936001, K941223, currently in commercial distribution.

Device Description: The GE Advance NXi PET System is a general purpose diagnostic PET scanning system for whole body imaging. It consists of a gantry, patient table, image acquisition hardware and software, and an operator display and interface console.

Indications for Use: The GE Advance NXi is intended for use in whole body, multislice, positron emission tomography diagnostic imaging.

Comparison with Predicate Device: The GE Advance NXi Positron Emission Tomography System is of a comparable type and substantially equivalent to the currently marketed GE Advance PET System. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended uses as the predicate device.

Summary of Studies: The device has been evaluated for electrical, mechanical, and radiation safety, and conforms with applicable medical device safety standards.

Clinical Tests: None required.

Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. Intended uses and fundamental scientific technology are the same as the legally marketed GE Advance PET System. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and EN 46001 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Therefore, it is the opinion of GE Medical Systems that the GE Advance NXi Positron Emission Tomography System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SUPPLEMENTAL- # 1

Public Health Service
November 26, 2013
12:40pm

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2000

D. Duersteler
Safety and Regulatory Engineering
General Electric Company
P.O. Box 414
Milwaukee, WI 53201

Re: K003849
GE Advance NXi PET System
Dated: December 11, 2000
Received: December 12, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Duersteler:

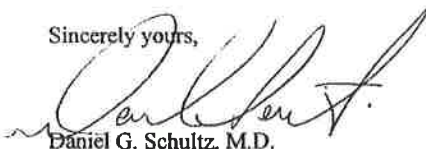
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

November 26, 2013

12:40pm

Special 510(k) Premarket Notification
GE Medical Systems - GE Advance NXi Positron Emission Tomography System
December 11, 2000

STATEMENT OF INTENDED USE

510(k) Number (if known): K003849

Device Name: GE Advance NXi Positron Emission Tomography System

Indications for Use


The GE Advance NXi is intended for use in whole body, multislice, positron emission tomography diagnostic imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801-109)

OR Over-The-Counter Use _____


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K003849

3. Document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: There is no other cardiac PET provider in the primary service area, with whom the applicant could share this service. The only other cardiac PET unit in the region is the Wellmont Health System in Kingsport, in adjoining Sullivan County. It is not as physically close to primary service area residents as Gray or Johnson City. It is not available to patients who are not in the practice of Wellmont Cardiology Services. It is also going to be used at full capacity by patients of Wellmont Cardiology, within three years. So alternate services in the region are not as accessible or available. They are likely to be comparable in terms of continuity, cost, and quality of care, for most referred patients.

4. (This criterion is not applicable because it pertains only to a proposed new mobile PET.)

5A. Need for "one additional stationary PET unit in an area" is likely if the utilization of existing PET providers was at or above 80% of their total capacity (i.e., at or above 1,600 procedures annually), as reported to HSDA most recently.

Response: Not applicable. The applicant is not proposing to open an additional PET unit in the area. The applicant's medical practice is proposing to acquire and operate the only PET service currently approved within in the Karing Hearts Cardiology primary service area.

In Section C(I)5 of this application, the applicant provides historic utilization for the ODC in Gray (Washington County), which provides the only such service in the primary service area. It attained 668 procedures in CY2012. The section also provides the PET utilization of all PET providers in or near the Tennessee primary service area. Only one has reported to the HSDA an annual utilization of 1,600 or more procedures.

5B. Applicants (for "one additional stationary unit in a service area") should perform at least 1,000 and 1,600 procedures per year in the first two years, respectively.

Response: This criterion is not applicable, because this is not an additional unit for the area. It is a proposed change of provider/owner for an existing, previously approved cardiac PET unit and service. Its use will be restricted to cardiac procedures, for the patients of a single practice. If it achieves an annual growth rate of 10% a year, it will reach a rate of 1,600 annual procedures in CY2024, its tenth year of operation.

6a. The PET unit must be FDA-certified for clinical use.

Response: Complies; documentation is provided in Attachment B.II.A.3.

6b. The PET's physical environment must conform to applicable Federal standards, manufacturer's specifications, and licensing requirements.

Response: Compliance in this regard is established by the architect's letter in Attachment C, Economic Feasibility-1, attesting to intended compliance with applicable codes, standards, and licensing requirements.

6c. The applicant should demonstrate how emergencies will be managed in conformity with accepted medical practice.

Response: Please see the applicant's emergency response protocols, in Attachment C, Need--1A.

6d. The applicant should establish protocols assuring that procedures are medically necessary and are not unnecessarily duplicative.

Response: Please see the applicant's medical necessity protocols, in in Attachment C, Need--1A.

6e. Medical Direction should be provided by a licensed physician Board certified in either Nuclear Medicine or Diagnostic Radiology. Licensure should be in place for handling radioactive pharmaceuticals and medical isotopes. Interpreting physicians should have documented experience and training, credentialing, and/or Board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Response: Dr. Jeffrey Schoondyke, whose C.V. is in the Attachments, is a Board certified cardiologist who has been Medical Director for the cardiac PET service at the Gray ODC for several years. He is trained and highly experienced in the use and interpretation of cardiac PET studies. Dr. Schoondyke will continue to be Medical Director of the cardiac PET service when it moves to his practice office in Johnson City. His practice already holds a license for handling radioactive substances, for nuclear medicine studies of other types that the practice currently performs.

6f. Applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. The medical director should be an active member of the medical staff of the hospital with which the agreement is made.

Response: Dr. Jeffrey Schoondyke is an active member of the medical staff of Johnson City Medical Center, with which Karing Hearts Cardiology will have a transfer agreement if this project is approved.

7. Submission of data to the HSDA

Response: The applicant commits to comply with the requirement for timely submission of the identified data to the HSDA Equipment Registry.

INDEX OF ATTACHMENTS

A.4	Ownership--Legal Entity and Organization Chart (if applicable)
A.6	Site Control and Documentation of Building Market Value
B.II.E.1.	Fixed Major Medical Equipment--FDA Approval Documentation
B.II.E.3	Major Medical Equipment-- Draft Lease; Market Value
B.III.	Plot Plan
B.IV.	Floor Plan
C, Need--1A	Documentation of Project-Specific Criteria <ol style="list-style-type: none">1. Qualifications of Dr. Jeffrey Schoondyke2. Qualifications of Dr. Melanie Davidson3. Emergency Response Protocols4. Medical Necessity Protocols5. Medical Director Specifications
C, Need--1.A.3.	Letters of Intent <ol style="list-style-type: none">1. ODC's Letter of Intent to Surrender CN1304-014 and to Cease Operation2. Letter of Intent from Radiopharmaceutical Vendor
C, Need--3	Service Area Maps
C, Economic Feasibility--1	Documentation of Construction Cost Estimate
C, Economic Feasibility--2	Documentation of Availability of Funding
C, Economic Feasibility--10	Financial Statements of Applicant
Miscellaneous Information	<ol style="list-style-type: none">1. TennCare Statistics2. PSA Demographic Data Source3. Articles on Cardiac PET Technology4. Medically Underserved Areas in the Project Service Area
Support Letters	

Factors for Special Consideration**8a. Service to Medically Underserved Areas**

Response: Medically Underserved Areas/Populations are areas or populations designated by the Federal Health Resources and Services Administration (HRSA) as having too few primary care providers, high infant mortality, high poverty and/or high elderly population.

At the end of the Attachment labeled "Miscellaneous Information", the applicant provides documentation of each Federally-designated "Medically Underserved Area" ("MUA") in the project's primary service area. These lists are from the HRSA website. They identify the following MUA's:

- Carter County
- Unicoi County
- Within Washington County: MCD's 90940/District 5; 91510/District 8; 91700 District 9. These are in the county's Bethesda Division Service Area.

8b. Higher than Average State Rate of Heart Disease

Response: The applicant is not claiming this special circumstance at this time. This is neither a new service for the area, nor an additional unit for the area; so justification of this type should not be deemed necessary.

8c. Safety Net Hospital; Children's Hospital; or Comprehensive Cancer Program

Response: The application is not by a safety net hospital, a children's hospital, or a hospital with a comprehensive cancer program.

8d. Commitment to Contract with One or More TennCare MCO's and to participate in Medicare.

Response: The payor mix of Dr. Schoondyke's practice, from which the cardiac PET's referrals will come, is currently approximately 60% Medicare and 6% TennCare. His practice contracts with all available MCO's in the area.

Page Nine
November 25, 2013

8. Section C, Need, Item 6

Does the projected PET volume consider that instead of being an ODC open to all comers versus now being limited to two (2) cardiologists at Karing Hearts?

Yes, the projection and accompanying narrative specify that this is referral data projected for two (2) cardiologists, and does not include any referrals to the service from outside the practice.

9. Section C. Economic Feasibility Item 1 (Project Cost Chart)

The letter from the Architect is noted. However, the address of the applicant in the letter is noted as N. State of Franklin Road. Please clarify.

Please see the explanation for this in response to your supplemental question #1 at the beginning of this letter. Local persons often add "North" to State of Franklin to indicate that they are located on State of Franklin Road north of US 231/Market Street.

10. Section C, Economic Feasibility, Item 4

Please provide a Historical Data Chart for Karing Hearts.

The requested chart with a notes page, numbered as pages 44a-44b, are attached following this page.

11. Section C, Economic Feasibility, Item 6B.

Table Ten is noted. However, it appears the average gross and net revenue charges in 2012 for Molecular Imaging Alliance, Gray is identical. Please clarify.

The table is in error. Attached following this page is revised page 48R, with Molecular Imaging Alliance's reported CY2012 gross and net revenues per procedure corrected to \$4791 and \$1855, respectively. That year the ODC remained under the ownership of Soteria Imaging. Mr. Rob Gregory acquired the ODC at the end of CY2012.

HISTORICAL DATA CHART -- KARING HEARTS CARDIOLOGY

November 26, 2013

12:40pm

Give information for the last three (3) years for which complete data are available for the facility or agency (SEE NOTE)

The fiscal year begins in January.

	Patient Encounters	Year 2011 2314	Year 2012 6512	Year 2013 9302
A. Utilization Data				
B. Revenue from Services to Patients				
1. Inpatient Services	\$			
2. Outpatient Services		1,705,926	4,816,252	6,206,680
3. Emergency Services				
4. Other Operating Revenue				
(Specify) <u>See notes page</u>				
Gross Operating Revenue	\$	1,705,926	4,816,252	6,206,680
C. Deductions for Operating Revenue				
1. Contractual Adjustments	\$	1,125,911	3,082,401	3,910,208
2. Provision for Charity Care (5%)		85,296	240,813	310,334
3. Provisions for Bad Debt		99,133	112,400	121,973
Total Deductions	\$	1,310,340	3,435,614	4,342,515
NET OPERATING REVENUE	\$	395,586	1,380,638	1,864,165
D. Operating Expenses				
1. Salaries and Wages	\$	190,960	558,824	624,888
2. Physicians Salaries and Wages		130,363	323,561	422,736
3. Supplies		2,438	12,360	35,302
4. Taxes		400	975	3,992
5. Depreciation		12,143	77,965	104,393
6. Rent		22,464	37,021	57,175
7. Interest, other than Capital		0	0	0
8. Management Fees		0	0	0
a. Fees to Affiliates		0	0	0
b. Fees to Non-Affiliates		0	0	0
9. Other Expenses (Specify) <u>See notes page</u>		129,959	314,422	448,842
Total Operating Expenses	\$	488,727	1,325,128	1,697,328
E. Other Revenue (Expenses) -- Net (Specify)	\$			
NET OPERATING INCOME (LOSS)	\$	(93,141)	55,510	166,837
F. Capital Expenditures				
1. Retirement of Principal	\$	0	26,539	54,830
2. Interest		8,034	17,130	15,510
Total Capital Expenditures	\$	8,034	43,669	70,340
NET OPERATING INCOME (LOSS)				
LESS CAPITAL EXPENDITURES	\$	(101,175)	11,841	96,497

Note: CY2011 is a partial year, in which Dr. Schoondyke left a local cardiology group to set up an independent practice.

HISTORIC DATA CHART
NOTES TO OTHER EXPENSES (LINE D9)

	CY2011	CY2012	CY2013
Employee benefits	15,163	28,360	36,844
General office supplies	31,723	74,362	75,119
Leasehold Im/Abandonmnt	0	28,253	0
Charitable Donations	5,145	15,365	17,389
Advertising Bus dev	44,763	22,954	14,942
Contracted Services	2,919	7,380	7,994
Meals and Entertainment	604	6,245	20,502
Utilities	6,739	36,989	69,012
Service repairs	1,090	10,391	15,281
Insurance/Licensing/Accreditation	7,245	18,356	28,998
Billing fee	10,721	39,788	27,524
Accounting	3,080	7,495	15,336
Legal	767	18,484	0
Owner Draws	0	0	119,900
TOTAL	129,959	314,422	448,841

C(II).6.B. COMPARE THE PROPOSED CHARGES TO THOSE OF SIMILAR FACILITIES IN THE SERVICE AREA/ADJOINING SERVICE AREAS, OR TO PROPOSED CHARGES OF PROJECTS RECENTLY APPROVED BY THE HSDA. IF APPLICABLE, COMPARE THE PROJECTED CHARGES OF THE PROJECT TO THE CURRENT MEDICARE ALLOWABLE FEE SCHEDULE BY COMMON PROCEDURE TERMINOLOGY (CPT) CODE(S).

Table Ten below compares this project's projected charges to the recently approved projected charges of Wellmont Cardiac Services' cardiac PET service in Kingsport, and Molecular Imaging Alliance's approved CON application to relocate its Cardiac PET ODC to Johnson City.

The projected average gross charge for this ODC in 2014 in Johnson City is projected to be higher than at the Gray location in CY2012. However, the ODC's projected average net operating revenue (receipts), which is its impact on payors, will be lower.

Table Ten: Comparative Gross Charges Per Cardiac PET Scan	
Provider	Average Gross / Net Revenue
Molecular Imaging Alliance, Gray (Soteria)	Actual 2012: \$4,791 / \$1,855
Wellmont Cardiology Services at Kingsport	Proposed, CY2014: \$3,678 / \$1,140
Molecular Imaging Alliance, Johnson City	Proposed, CY2014: \$3,133 / \$1,675
Karing Hearts Cardiology, Johnson City	Proposed, CY2015: \$3,044 / \$1,644

Source: HSDA records; Applicant's Projected Data Chart, this application.

The following page contains Table Eleven, a chart showing the most frequent procedures to be performed, with their current Medicare reimbursement, and their projected Years One and Two utilization and average gross charges.

Page Ten
November 25, 2013

12. Section C, Economic Feasibility, Item 9.

a. The TennCare/Medicaid Gross Revenue of \$123,830 or 6% in Year One is noted. However, please clarify if that includes revenue from Virginia Medicaid.

The TennCare/Medicaid Gross Revenue of \$123,830 does include revenue from Virginia Medicaid. Gross Revenue from patients who are covered by Virginia Medicaid represent less than 1% (0.15%) of the applicant's total Gross Revenue.

b. Please indicate the gross revenue the applicant expects from Virginia Medicaid patients.

Approximately \$3,095 in CY2015

Approximately \$3,232 in CY2016

13. Articles

The applicant has provided a 4-page Article titled "*Single-photo Emission Computed Tomography*" from Wikipedia. Please clarify if Wikipedia is a reliable source for information regarding medical equipment.

The referenced article is about SPECT imaging, which cardiac PET imaging is steadily replacing. It was provided to the HSDA in Molecular Imaging's approved application CN1304-014. The applicant is seeking to be consistent with the prior application. In the judgment of Karing Hearts Cardiology, all the articles provided can be helpful background material for the Board. Wikipedia often provides language that is easier for some persons to understand than the language used in peer-reviewed medical journals. Journal articles and a magazine article were also attached.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please FAX or telephone me so that we can respond in time to be deemed complete.

Respectfully,



John Wellborn
Consultant

NOV 26 '13 PM 12:34

SUPPLEMENTAL- # 1

**November 26, 2013
12:40pm**

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY: KARING HEARTS CARDIOLOGY--CARDIAC PET SERVICE

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

John Wellborn
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 26 day of NOVEMBER, 2013,
witness my hand at office in the County of DAVIDSON, State of Tennessee.

[Signature]
NOTARY PUBLIC

My commission expires 1-11, 2017.

HF-0043

Revised 7/02

